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DG XXIV

**Consumer Policy and
Consumer Health Protection**

1997

Annual Report

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In view of what has been for DG XXIV a particularly eventful year in 1997, it has been decided to publish a first annual report. This report covers the period April 1997 through to March 1998. Following its reorganisation in April 1997 in the wake of the BSE crisis, DG XXIV – apart from consolidating its activities in the more traditional “consumer policy” area – had to take on major new responsibilities, especially with regard to consumer health protection. Subsequently, two new directorates were set up to focus more closely on the problem of food safety. DG XXIV now has at its disposal not only a completely new structure of scientific advice (Directorate “B”), but also a newly established body to monitor the Member States’ control systems in the field of veterinary and plant health control, the Food and Veterinary Office (“FVO”) in Dublin. The aim of the Office is to establish the best possible food surveillance system, as well as food safety in general. This is based partly on regular missions within the EU and in third countries. A third new directorate now deals with the coordination of horizontal questions and, more importantly, with resources.

One of DG XXIV's major challenges since its restructuring has been the increasing workload following its new health protection mission. A substantial part of its efforts was devoted to the relevant activities of the European Parliament and, principally, to the work of the European Parliament Temporary Committee on the follow-up of recommendations on BSE. As a result, DG XXIV produced several reports on the handling of the BSE crisis; the final consolidated report prompting a positive reaction from the European Parliament in November.

Moreover, DG XXIV was actively involved in the elaboration of new scientific positions for the Commission on current issues such as Specified Risk Materials (SRM), Genetically Modified Organisms (GMO), phthalates in toys and the Water Framework Directive.

Furthermore, a considerable number of specific BSE-related missions were undertaken by the FVO within the EU and third countries.

DG XXIV had to absorb a large number of new staff, necessitating a move to a new building. The number of staff rose from 96 to 322 officials, 234 of whom were already in appointment as of 31 March 1998 (88 of them in Ireland). It is expected that in the final phase in 1999, the staff level will be around 350 officials (of which 170 in Ireland). Moreover a major transfer of colleagues to the newly established FVO in Dublin had to be organised from September 1997 onwards. This major logistic exercise was not completed without difficulty and has only provided a temporary solution.

The Office, currently with a staff of around 70, will continue to grow and will move from its present location in Dublin to the definitive Grange site outside Dublin, probably towards the end of the year 2000.

In parallel to these new responsibilities, DG XXIV has continued to be very active in “traditional” consumer policy issues.

In 1997 and early 1998, four important directives (“Distance Selling”, “Comparative Advertising”, “Unit Pricing” and “Consumer Credit”) were adopted. Work on the “Injunctions” directive is about to be finalised and efforts in preparing the ground for new measures and legislation focussed on:

- Financial services
- Guarantees

In the light of the transition to the Euro, a major information action (the Forum on “The Consumers and the Euro”) was held in Luxembourg in December with a view to preparing consumers, and the European Union's citizens in general, for its introduction in 1999.

This activity report will be deliberately concise and will confine itself to summarising the core activities. It will be published in a regular annual version as from this year.

The structure of the report reflects the tasks performed by the various directorates.

Horst Reichenbach
Director-General

*“Consumer Policy and
Consumer Health Protection”*



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● Risk Evaluation ●

Directly attached to the Director General's office is the "Risk Evaluation" unit. This reflects the priority concern of the Commission to protect consumer health, particularly as regards food safety.

The need to establish a structure dealing with the highly sensitive issue of risk evaluation was identified in the Communication of the Commission on "Consumer Health and Food Safety" of 30 April 1997. Since then, the unit has progressively expanded both in terms of staffing and other resources. Moreover, a network of external experts in a broad variety of specialised areas is being set up with the aim of making scientific advice quickly available in emergencies.

The "Risk Evaluation" unit plays a major forward-looking role in identifying potential and emerging health risks; in so doing, it contributes to a pro-active, rather than reactive, approach in dealing with issues related to consumer health.

The scientific committees carry out the routine risk-assessments in their area of competence, such as food, animal feed, cosmetics etc. The "Risk Evaluation" unit, however, is geared towards reacting rapidly to immediate problems in order to provide decision-makers with prompt advice on specific questions. This is the case whenever safeguard-clauses are provided for in order to limit the risks of food-borne disease from imported products. Recently the "Risk Evaluation" unit contributed to assessing the risks arising from the cholera epidemic in Africa and avian influenza in Hong Kong.

The "Risk Evaluation" unit also works in close collaboration with the scientific committees on matters of particular concern or major political interest. In 1997, the composition of the Euro coins needed to be finally agreed, but consumers had expressed concern about the nickel content of the alloy to be used for the 1 and 2 Euro coins, since in certain circumstances nickel can give rise to allergies. The "Risk

Evaluation" unit was able to rapidly mobilise the necessary resources to carry out laboratory tests on samples of coins.

This strengthened the position of the Scientific Committee for Toxicity, Ecotoxicity and the Environment to assess the risk of nickel allergy in consumers handling the coins, and ultimately led to the public being reassured. In other cases, the unit has been able to perform extensive documentary research in support of the scientific committees.

The EU has banned the import of meat from hormone-treated animals. Under a recent ruling by the World Trade Organisation (WTO), the EU is now obliged to provide scientific justification for this ban. The "Risk Evaluation" unit is responsible for the coordination of risk assessment on hormones which is being carried out as a follow-up to the WTO ruling.

The unit actively contributes to the development of harmonised procedures for risk assessment at international level in the Codex Alimentarius and the OIE (Organisation Internationale des Epizooties) as well as in bilateral discussions with the United States, Canada, Australia and New Zealand. In this sense, it plays an interface role between these organisations or countries and the scientific committees involved in risk assessment.

In the field of inspections, the unit contributed to the development of a risk-ranking approach in order to determine priorities, to focus on the highest risk situations and to make optimal use of the limited human resources available.

Finally, a number of documents aimed at informing the public and the press were prepared regarding the final report of the Commission to the European Parliament on BSE, the outcome of meetings of the scientific committees as well as other consumer related issues.

1. ● Community Action In Consumers' Interest ●

Directorate A's ("*Community Action in Consumers' Interest*") stated mission is to prepare and follow up the European Union's policy for protecting consumers' interests, while at the same time continuing and developing what is considered to be «traditional» consumer policy.

1.1 General Remarks

Activities in 1997 have been marked by the restructuring of the Directorate. This will allow, on the one hand, a better adaptation of the structure to its new competences and, on the other, a clearer definition of priority actions.

In particular, it will be important to develop, more systematically and thoroughly, the principles of consumer policy and

its integration in other Community policies, as well as an evaluation of the ways in which it is being implemented and the impact it has in the Member States. To this end, a unit specially in charge of the development of consumer policy has been created. Another unit has been set up with responsibility for agricultural, food product and health issues. It will closely monitor the Common Agricultural Policy, especially measures concerning the enterprise reform, as indicated in the guidelines of Agenda 2000.

It is also important to note, that the new version of Article 129A (Article 153 of the Amsterdam Treaty) will have a major impact on consumer policy. It is therefore important to study the implications involved, even before the ratifica-

tion of the Amsterdam Treaty. It is envisaged that a working group composed of both internal and external experts will be set up accordingly.

An evaluation exercise is presently underway. It has resulted in a "stock-taking" document that will be presented to the European Parliament and the Council during the first semester of 1998. On this basis, a "perspectives" document will be prepared that will establish the future priorities of the Commission in terms of a framework for a Consumers' Policy for 1999–2001.

1.2 Specific Sectors

1.2.1 Protection of Economic Interests

Defence of the economic interests of consumers has been a continuing priority during 1997. In this context, a series of legislative measures have been prepared and some of them were adopted during 1997 and early 1998.

The Directive on "Distance selling" was formally adopted in May 1997, and a series of follow-up conferences and presentations have been given to interested parties.

The Directives on "Comparative Advertising" and "Price Indications" were adopted in October 1997 and February 1998 respectively, while the Directive on "Transborder Injunction in Consumer Related Infringements" is completing the second reading procedure and should be adopted within a few months. Studies were conducted on the economic impact of the Directives on "Price Indication" and "Guarantees". As for the latter directive, work is proceeding both in the Council and the European Parliament on the basis of the proposal submitted by the Commission in July 1996.

1.2.2 Food Products and Health

Public health, the economic burden of the price of food on a family budget, consumer choice and confidence remain the major concerns of the general public. The integration of these elements of consumer policy in other Community policies, such as the Common Agricultural Policy (CAP) and the Common Fisheries Policy (CFP), will be a priority, particularly with regard to the ongoing reforms in these areas.

In parallel, during 1997, there has been an increase in foodstuffs control. The global report on the official control of foodstuffs operated by national authorities has led to a number of recommendations by the Commission. The Foodstuffs Inspection Services have focussed their activities on the mechanisms put in place by the Member States for the control of foodstuffs of non-animal origin imported into the Union from third countries and further recommendations will be formulated in the near future based on the results.

In addition, the Food Rapid Alert System has been operative by the Commission on a 24-hour basis. It has enabled the Commission to inform the Member States as to the presence on their territory of foodstuffs which may threaten the health of consumers. The information thus obtained by the

Commission through this "Rapid Alert System" has been used, *inter alia*, to determine the Commission's global inspection priorities and on-the-spot-checks in co-operation with the official national control services.

1.2.3 Financial Services and the Euro

The main event of 1997 was the adoption by the Commission of the Communication on "Financial Services: Enhancing Consumer Confidence". It expressed the increasing importance of financial services for consumers, and included a comprehensive programme of legislative and other measures.

It is in this framework that a draft directive is being prepared in conjunction with the Directorate-General for the Internal Market (DG XV) on "Distance Contracts". Work has also continued in areas relating to "Insurance Intermediaries" and "Unregulated Financial Intermediaries", where a directive is under consideration.

Other areas of activity in 1997 related to the adoption of the "4th Motor Insurance Directive – Visitors" and to the adoption of the directive on "Consumer Credit". A series of studies on usury, publicity of financial services addressed to young people, doorstep-selling of financial services, the inclusion of mortgage credit in consumer-credit legislation and the application of data-protection rules on consumer credit, were initiated and concluded in the autumn of 1997.

The Consumer Council launched a discussion on the quality of the Annual Percentage Rate (APR) of charge, and work on the "Single Formula for Calculating the APR" Directive was completed.

Work is also continuing on "New Means of Payment", following the Recommendation concerning "Transactions by Electronic Payment Instruments and in particular the Relationship between Issuer and Holder", adopted in July 1997 by the Commission.

The development of dialogue instruments between service providers and consumers has led to the development of a pilot project on "Information for Consumers on Mortgage Credit, National and Across Borders".

Activities in connection with the adoption of the Euro have been marked by important actions, especially the preparation of diverse working documents. During 1997 two main expert groups on the Euro were created: the "Euro" group of the Consumer Committee and the Psycho-sociologists group.

The "Euro" group of the Consumer Committee was put in place to analyse the global process of the passage to the Euro for consumers. It produced a first report called the "Report of the Working Group of the Euro for the Attention of the Consumer Committee" in September 1997 and a summary document on the position of the Consumer Committee "Assuring the passage of consumers to the Euro", adopted in November 1997.

The Psycho-sociologists group involving psychologists, sociologists, economists and legal experts held a series of meetings and produced a document entitled "The Passage to the Euro: Assuring the Acceptation and the Confidence of Consumers". In

December 1997 a Round Table took place with 300 participants in Luxembourg on the theme "*The Consumer and the Euro*", which allowed for the presentation of the consumer position on the Euro.

1.2.4 Consumer Safety and Environment

Horizontal responsibilities of consumer safety tasks were streamlined during 1997. The responsibilities for certain product directives such as "*Safety of Toys*", "*Cosmetic Products*" and "*Textile Names*" were therefore transferred to the Directorate-General for Industry (DG III) in the spring of 1997.

A series of notifications on dangerous products (54) under the RAPEX/REIS system and on general product safety (7) were dealt with in 1997. These concerned different issues that could endanger the health and safety of consumers. Other notifications concerning voluntary measures (20) were distributed for information. In addition, pursuant to the relevant provision of the Directive on "*General Product Safety*", the Emergency Committee met twice in 1997. Among other issues, it discussed problems related to non-edible items in foodstuffs and to softeners in plastic products intended for children.

The decision on the EHLASS-system (Home and Leisure Accident Surveillance System) came to an end at the end of 1997. Plans were set up for its continuation, including provision for developing and upgrading the information-flow.

Specific problems were tackled with non-legislative instruments. These included such issues as "*carbon monoxide poisoning*" and the "*toxic-shock syndrome*", where special action was called for by the European Parliament. After indications on potential dangers had been received through the procedures, as laid down by the Directive on General Product Safety and/or through the EHLASS data, mandates were endorsed for the development of standards for "*baby-walkers*", "*child-care articles*" and "*oil-lamps*". In addition, a study on "*flammable nightwear*" was initiated. Projects were started in such problematic areas as "*Enforcement/Market Surveillance*" and "*Administrative Co-operation and Information Exchange with Third Countries*", especially those of Central and Eastern Europe.

In the environmental and sustainable development areas, information actions to stimulate a public debate on more sustainable consumption patterns were launched in Spain, Italy and Greece. A pilot programme to test the quality of drinking

water in urban areas in three Member States, as well as a study on green product claims, are being carried out. Work continues on policy development, including consultation with partners as well as information gathering from Member States. A number of projects undertaken by national and international partners for both safety and environmental issues have also been initiated and co-financed.

1.2.5 Integration in other Community Policies

Active initiatives have been taken in 1997 to enhance the integration of consumer protection requirements for the definition and implementation of other Community policies and activities. This has led to major efforts to ensure that consumer interests are not overlooked, especially in such major areas as the internal market, competition policy, services of general interest, universal service and the Information Society.

As regards services of general interest, work and co-operation with other services continued in the areas of telecommunications, energy, transport, postal services and broadcasting. Efforts were made to include in the diverse initiatives of other Community policies such issues relating to consumer interests as choice, quality, openness, accessibility and information, possibility of redress, participation, equal treatment, cohesion and quality and permanence of services. Special attention was also paid to consumer protection with regard to universal service.

In the area of the Information Society, the objective has been to ensure that consumer interest is integrated in other Community policies, since work has concentrated, so far, on technological, industrial, commercial and sectoral aspects and *has not put the individual consumer at the centre of concern.*

Constructive contributions were made on numerous subjects ranging from the Ministerial Declaration on Global Telecommunication Networks, via the Internet Domain Name System, to the question of Convergence of Audio-Visual, Telecommunications and the Information Technology Sectors. Work has also continued in order to develop a specific policy document on the "*Consumer Dimension of the Information Society*", and financial support has been provided for various external organisations that have developed projects related to serving consumer interests using new communication technologies, or to demonstrating the benefits offered to consumers by the Information Society.

2. ● Scientific Health Opinions ●

Directorate B's ("*Scientific Health Opinions*") responsibilities are of particular interest to consumers with regard to the emphasis put on consumers' health protection and food safety in the wake of the BSE crisis.

The development of the internal market and the globalisation of the economy has a major impact in the food sector

and challenges the European Union to develop a new food policy which ensures the safety of foodstuffs and, thereby, the protection of consumer health. The BSE crisis has clearly illustrated the need to reinforce consumer health protection at Community level in order to restore consumer confidence in the safety of food.

The Commission accepted this challenge. In his speech of 18 February 1997 before the European Parliament, 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".

The new approach by the Commission on consumer health and food safety was laid down in the Commission's Communication of 30 April 1997 "Consumer Health and Food Safety". In this Communication, the Commission set out, *inter alia*, the following general principles as preconditions for successful completion:

- Separation of legislative responsibility from that of scientific consultation,
- Separation of legislative responsibility from that of inspection,
- Transparency and widely-available information throughout the decision-making process.

The instruments to achieve the new food policy are:

- Scientific advice, following the principles of excellence and independence of the members of the scientific committees, and transparency of their scientific advice,
- Risk analysis,
- Control and inspection.

In order to create the organisational basis for these changes, the Commission services were restructured with the result that responsibility for the relevant scientific committees, and for inspection and control, was placed under the authority of the Commissioner for Consumer Policy and Health Protection, and thus – at operational level – under the authority of the relevant Directorate-General (XXIV).

2.1 Initiatives

During the period April 1997 - March 1998, Directorate B took the following initiatives to implement new political strategy by creating a new structure for the scientific committees, which comprise:

1. the Scientific Steering Committee (SSC)
2. the eight specialised Scientific Committees (SC)

A key-element in the reorganization of the scientific committees was the development of a structure that allows all food-safety and consumer-health aspects to be taken into consideration, while ensuring a wide distribution of scientific competence between the committees. Moreover, this structure guarantees close co-operation and co-ordination between the work of the respective committees.

The Commission requests scientific advice in all cases provided for under Community law. However, the new structure makes it possible for the Commission to ask for advice from the scientific committees in respect of all questions which are

of importance to the decision-making process with regard to consumer health protection.

An outstanding example of this is the scientific advice by the Scientific Steering Committee concerning BSE, for which there is no obligation under Community law.

The task of the scientific committees consists above all in evaluating possible risks to the health of the consumer ("risk assessment") on issues submitted to them. It is incumbent on the Commission to propose the appropriate measures ("risk management") to be taken. In addition, the scientific committees have – *ex officio* – the competence to draw the attention of the Commission to issues which they find may constitute such risks.

The independence of the members of the Committees is ensured throughout their mandate and for each opinion. Consequently, at the beginning of their term of office, members sign a declaration stating interests that may be considered prejudicial to their independence. This declaration is renewed every year. Each committee member is also obliged to declare potential conflicts of interest with any individual agenda-item at each meeting.

2.2 Scientific Steering Committee (SSC)

By its Decision of 10 June 1997 (97/404/EC)¹ the Commission created the Scientific Steering Committee. It is composed of eight individually appointed members and the chairmen of the eight scientific committees.

The members of the SSC, who are not chairmen of the eight scientific committees, were appointed by the Commission in its Decision of 29 July 1997 (C 235 / 07)².

On 19 June 1997³, a call for expressions of interest was published for the membership of the SSC. It addressed all scientists irrespective of their nationality. The criteria for scientific excellence required the highest level of competence covering a broad range of disciplines and professional experience, primarily in an international and interdisciplinary environment. More than 150 applications were received. A selection committee was established under the chairmanship of a scientist of international renown. The committee selected 24 scientists from among whom the Commission then nominated eight as members of the SSC⁴.

The first meeting of the Committee took place on 21 November 1997.

The SSC has the following tasks:

Firstly, to assist the Commission in the co-ordination of the work of the scientific committees.

¹ Decision 97/404/EC of 10 June 1997 setting up a Scientific Steering Committee O.J. No L 169 of 27.6.97 p. 85

² O.J. No C 235 of 2.8.97 p. 5

³ O.J. No C 187 of 19.6.97 p. 6

⁴ Decision of 29 July 1997 O.J. No C 235 of 2.8.97 p. 5

Secondly, the SSC assists the Commission in the identification of those areas in which it would be advisable to provide for obligatory consultation of the scientific committees.

Thirdly, in the field of consumer health, the SSC provides scientific opinions for the Commission on questions not covered by the mandates of the other Committees, particularly in the multidisciplinary aspects of transmissible spongiform encephalopathies and of bovine spongiform encephalopathy (TSE/BSE). To this end, an ad hoc "TSE/BSE" group was set up under the responsibility of the SSC.

The SSC can make a preliminary opinion, which is diffused on the INTERNET in order to collect the reactions of the interested public.

Since November 1997, the SSC has adopted several important opinions on BSE matters:

- 8/9 December 1997: Report on the UK Date Based Export Scheme and the UK proposal on Compulsory Slaughter of the Offspring of BSE-cases,
- 8/9 December 1997: Listing of Specified Risk Materials: a scheme for assessing relative risks to man,
- 23 January 1998: Opinion of the SSC on defining the BSE-risk for specified geographical areas.

2.3 The Eight Different Scientific Committees and Their Mandates

The eight scientific committees were created by the Decision of the Commission of 23 July 1997 (97/579/EC)⁵. Their competence covers all areas of food safety including primary products of animal and vegetable origin, animal health and animal welfare, consumer goods, particularly cosmetic products, medicinal products, and all issues concerning toxicity, ecotoxicity and the environment.

The selection of the members of the eight scientific committees followed the same principles as for the selection of the SSC members. On 1 August 1997, the Commission published a call for expressions of interest⁶ which specified the role of each individual Scientific Committee and the necessary specialised knowledge required. A selection committee was formed. Under the chairmanship of the eight members of the SSC, the committee selected from some 850 applicants the 40 most suitable scientists for each of the eight scientific committees.

From this list, the Commission nominated the members⁷. Special attention was given to ensuring that the various scientific disciplines were represented in a well-balanced manner within the individual Committees. The members were appointed by Decision of the Commission of 4 November 1997⁸.

The first meetings of all the committees were held before the end of 1997.

2.3.1 Scientific Committee on Food (SCF)

The SCF assists the Commission in examining scientific and technical questions concerning consumer health and food safety associated with the consumption of food products; in

particular, questions relating to toxicology, hygiene across the food production chain, nutrition and the application of agri-food technologies, as well as questions relating to materials coming into contact with foodstuffs (through packaging, for example). The consultation of the SCF is a prerequisite laid down in most areas of Community food legislation relating to the internal market and ensures that proposals for measures in this areas satisfy the need for a high level of public health protection.

The present membership of the SCF comprises 17 scientists. The SCF is assisted by 8 working groups.

Community legislation covers food additives, materials that could come into contact with food, such as packaging, flavourings, contaminants, novel foods and novel-food ingredients, dietetic foods, and the hygiene of foodstuffs.

The SCF has issued many opinions in these areas and also with regard to food additives permitted in the EU (these correspond to the "e"-number system used to indicate the presence of food additives in the labelling of food); novel foods (in particular the marketing of maize and the relationship between scientific data and the labelling of genetically modified foods and their derived products); and the principles for the development of risk-assessment of microbiological hazards and contaminants such as lead, cadmium, aflatoxins and nitrate.

2.3.2 The Scientific Committee on Animal Nutrition (SCAN)

The SCAN responds to scientific and technical questions concerning animal nutrition, its effect on animal health and the quality and health of products of animal origin, and concerning the technologies applied to animal nutrition. It comprises 18 scientists.

Substances that are to be authorised by Community legislation concerning feed additives are first examined by the SCAN in respect of their safety and, in particular, their potential risk to the consumer of animal products.

Feed additives represent a wide range of substances including, *inter alia*, micro-organisms, enzymes, antimicrobials, each class requiring its own specific risk assessment considerations.

In addition, the SCAN is frequently asked to give urgent opinions on submissions made by Member States that request amendments to Community legislation on feed additives (application of safeguard clauses).

2.3.3 The Scientific Committee on Animal Health and Animal Welfare (SCAHAW)

The SCAHAW responds to scientific questions relating to animal health and disease and animal welfare. It also

⁵ Decision 97/579/EC of 23 July 1997 setting up scientific committees in the field of consumers health and food safety O.J. No L 237 of 28.8.97 p. 18

⁶ O.J. No C 233 of 1.8.97 p. 3

⁷ Decision of 4 November 1997 O.J. No C 342 of 12.11.97 p. 8

⁸ O.J. No C 342 of 12.11.97 p. 8

responds to questions relating to zoonotic diseases, i.e. diseases transmissible from animals to man, except in the case of diseases shown to be food-borne, in which case the competent committee is the Scientific Committee on Veterinary Measures related to Public Health.

The SCAHAW is composed of two sub-committees dealing with Animal Health and Animal Welfare, and comprises 19 members.

In order to ensure that, with regard to animal-health questions, animal-welfare aspects are also taken into consideration when adopting an opinion (and vice versa), draft opinions prepared by either of the two sub-committees are submitted for adoption by the full SCAHAW.

On animal health issues, the committee may examine all aspects of animal diseases. Zoonotic diseases are particularly important, a good example being the case of rabies. Here, the committee has reported on developments in the anti-rabies campaigns in the European Union and recommended more suitable ways of allowing movement of pet animals into rabies-free areas.

As regards animal welfare, the Committee has in the past produced reports on several major issues, e.g. the welfare of calves and the welfare of intensively-kept pigs, transport of animals and on more specific issues, e.g. stunning methods at the time of slaughter.

2.3.4 The Scientific Committee on Veterinary Measures relating to Public Health (SCVPH)

The SCVPH is responsible for scientific and technical questions concerning consumer health and food safety, and those relating to zoonosis (diseases and/or infections which are likely to be transmitted from animals to man), toxicology, veterinary and, notably, hygiene measures applicable to the production, processing, and supply of food of animal origin. The SCVPH comprises 16 scientists.

Examples of questions which are still pending in the areas of veterinary public health covered by the committee are: microbiological criteria for food of animal origin, residues of veterinary drugs and toxic substances, detection methods for pathogens in food of animal origin.

2.3.5 The Scientific Committee on Plants (SCP)

The role of the SCP is to provide the Commission with informed opinions on scientific and technical matters relating to plants intended for human or animal consumption and to the production of non-food products with characteristics liable to affect human health or the environment. This involves the assessment of current and proposed agricultural practices and includes consideration of questions relating to plant protection and plant breeding, including conventional and biotechnological methods.

The committee comprises 15 scientists.

Questions addressed to the committee have concerned genetically modified plants (plant GMOs) and plant protection products.

2.3.6 Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP)

The SCCNFP assists the Commission in examining the complex scientific and technical problems surrounding the drawing up and amendment of Community rules governing the composition, manufacture, packaging and labelling of cosmetic and non-food products marketed in the European Union. Where cosmetic products are concerned, the consultation of the SCCNFP is compulsory.

The committee consists of 16 members.

The work of the SCCNFP can be divided into cosmetic products and non-food consumer products. Five working parties have already been set up to deal with Alternative Methods to Animal Testing, Hair Dyes, the Inventory of Cosmetic Ingredients, Preservatives, Colorants & Fragrances and UV-filters.

2.3.7 Scientific Committee on Medicinal Products and Medical Devices (SCMMD)

The SCMMD examines scientific and technical questions relating to Community legislation concerning medicaments for human and veterinary use and medical devices, without prejudice to the specific competence given to the Committee for Proprietary Medicinal Products and the Committee on Veterinary Medicinal Products of the European Agency as regards the evaluation of medicaments and concerning medical material and equipment.

The committee comprises 16 members.

The Commission consults the committee on questions of individual interest connected to consumer health, even if this is not explicitly envisaged in the legislation.

The following questions are currently under discussion: the risk/benefit analysis of medical devices whose manufacture involves the use of materials with specified risk, as well as possible alternatives to this type of appliance, safeguard clauses, the safety measures to be adopted regarding the use of gelatine for the manufacture of medicines and medical devices, possible transmission of CJD by blood and several concepts of "orphan drugs", starting materials, etc.

2.3.8 Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE)

The SCTEE responds to scientific and technical questions relating to the examination of the toxicity and ecotoxicity of chemical, biochemical and biological compounds whose use

may have harmful consequences to human health and the ecosystems. The brief of the CSTEE also includes the environment in a broad sense.

The CSTEE comprises 15 members. Several ad hoc working groups have been formed to answer specific opinion requests; the following are examples: "Phthalates in toys", "Chrysotile asbestos", "Water Framework Directive", "Tin, Arsenic and Cadmium", "Endocrine disrupters", "Pentachlorophenol" and "Creosotes".

2.4 The Work of The Eight Scientific Committees

The committees are entitled to establish working groups and to nominate *rapporteurs* to prepare opinions. In addition, the committees can consult external experts if specialised knowledge is needed.

The ever-increasing complexity of food-processing requires an integrated approach and close co-operation between the committees. The Commission Decision setting up the Scientific Steering Committee and the 8 scientific committees provides for and ensures such co-operation:

- each chairperson of the eight scientific committees informs the SSC of the activities of his/her committee,
- members of other scientific committees may provide assistance as external experts,
- a joint working group may be set up with one or more of the other committees if the question has a bearing on the field of competence of one or more of the other scientific committees. In case of major differences of opinion, the SSC will produce a summary.

The greatest possible transparency is ensured in various ways in the work of the scientific committees. Names of committee members, the agendas, the minutes of the meetings and the opinions are likewise disseminated via INTERNET (http://europa.eu.int/comm/dg24/health/sc/index_en.html).

2.5 Cooperation between DG XXIV and other DGs

The separation of scientific consultation from the responsibility for legislation requires close collaboration between DG XXIV and the Directorates-General responsible for the preparation of legislative proposals. In principle, it is their task to identify the questions which are to be submitted to the scientific committees and to take account of scientific advice in the preparation of the legislative proposals. It is incumbent on DG XXIV to obtain the opinions of the scientific committees.

Beyond that, and in the framework of its competence for consumer protection, DG XXIV follows the implementation of the scientific advice during the process of drawing up the Commission's policy and, in particular, during the preparation of proposals for legal texts which affect consumers' health.

Early participation of DG XXIV in the process is thus particularly important. Co-operation, however, need not only be limited to the areas in which consultation of the scientific committees is mandatory by Community law. The new approach of the Commission to consumer-protection policy requires DG XXIV to take an active part in all matters which have particular relevance to consumer health and food safety, even when consultation is non obligatory.

Emphasis is also placed on co-operation with other DGs in the preparation of the Commission's political objectives and the establishment of priorities in the area of consumer policy. Consultation of the scientific committees results in Community legislation being based on the best available scientific evidence.

To ensure this close co-operation between DG XXIV and the other DGs, an operations manual was prepared in 1997 between DGs III, V, VI and DG XXIV and a similar one is in preparation with DG XI. A memorandum of understanding concerning institutional support for DG XXIV from the Joint Research Centre is also in preparation.

3. ● Resources and Coordination ●

Directorate C's ("*Resources and Coordination*") mission is to ensure the coordination of horizontal questions, ranging from *budgetary coordination and management of resources to responsibilities such as legal matters, development of consumer information, education and representation, relations with the European Parliament, the European Council and the other institutions, as well as liaison with the Food and Veterinary Office (FVO) in Dublin.* Another of the Directorate's tasks is the integration of the consumer policy dimension *in relations with third countries and countries with economies in transition.*

3.1 Budgetary Coordination and Management of Resources

3.1.1 A New Presentation of the Budget

- In April 1997, the Commission requested a Supplementary and Amending Budget (SAB 1/97), putting at 97 the number of new posts and 500 000 ECU the additional operating appropriations needed to implement the new guidelines on consumer health.

At the end of November, Parliament and the Council decided to create 35 new posts and to provide the 500 000 ECU requested.

- In April 1997, the preliminary draft budget for 1998 was also amended to accommodate the new guidelines.

In the framework of budgetary rigour, and hence practically unchanged funding in the order of 20 Mio ECU, more than one-third of the resources were reallocated to fund the "health" sector of the activities.

At the end of 1997, approved appropriations were approaching the amount requested by the Commission (20.87 as opposed to 21.5 Mio ECU).

- The financial year 1999 should be the first to fully reflect the changed guidelines. The Commission, in its preliminary draft budget for 1999, put needs at 22 million euros, an amount which still constitutes a modest proportion of the Community budget (0.02%).

The presentation, in only two budget lines, highlights the two main strands: promotion of consumers' interests (B5-100 = 12.8 Mio ECU) and consumer health and safety (B5-103 = 9.2 Mio ECU).

3.1.2 Greater Transparency in Implementation

- There has been a major drive to analyse needs and to rank priorities, together with the other political players (organisations, institutions, specialists) and also with an eye to evaluating achievements to date (EHLASS, information centres, pilot projects on access to justice).
- The Commission's own-initiative actions have focused on the top priority themes, the objective being to reinforce the impact on the public. In some cases, notably in the awareness-raising campaigns, the work has been done in partnership with consumer organisations.
- The relative role of subsidies has been diminishing in the context of these streamlining operations. On the basis of calls for presentation of projects, published in the Official Journal and which indicated the procedures to be followed, as well as the selection criteria, 101 projects were selected for 1997 (for a total of 7.7 Mio ECU) and 64 for 1998 (for a total of 7.1 Mio ECU), with the emphasis on projects of high quality possessing a strong Community dimension.
- All these trends are reflected in the proposal for a European Parliament and Council Decision establishing a general framework for Community activities in favour of consumers (COM(97) 684 final), which the Commission presented on 28 January 1998 (OJ C 108, 7.4.1998).

This general framework puts at 114 Mio ECU the appropriations required for the 1999-2003 period.

3.2 Management of Resources And Reorganisation of DG XXIV

In April 1997, following a Commission Decision, the new DG XXIV "Consumer Policy and Consumer Health Protection" came into being. From this date, the management of the scientific committees in the field of health, the Office for the Control and Audit of Product Quality (subsequently renamed the Food and Veterinary Office), and the responsibility for the Evaluation of the Health Risk were regrouped within the competence of this service. A new "Resources" Directorate was also created.

The Food and Veterinary office was relocated to Ireland in September 1997, where it is presently housed in offices in Blackrock in the south of Dublin. The permanent location at Grange, approximately 35 km north west of Dublin, should become available within the next two years.

The new Members of the eight scientific committees and the Scientific Steering Committee were appointed by the Commission in 1997 and, over the course of the following months, became fully operational.

Two further modifications of the organigramme have taken place during the course of the year:

- the responsibility for legal aspects of work in certain industrial sectors (textiles, labelling, toys and cosmetics) was transferred to DG III;
- Directorate XXIV/A was completely reorganised in order to reflect the Commission's new approach to work, especially in the areas of food health, the new tasks attributed to DG XXIV by the Treaty of Amsterdam (integration of consumer policy in other Commission Policies, follow-up of Member States' Consumer Policy) and its increased responsibility in the areas of education and consumer representation.

3.2.1 Staff Levels

In April 1997, the new DG XXIV had a staff complement of 96 officials to which were immediately added a further 94 officials transferred from other Commission departments (DG III, V, VI and XI) to cover the new areas of competence.

During the course of the period in question, and in accordance with the report made early in 1997 by the Commission's General Inspection Service, further posts have regularly been made available to DG XXIV until, as at 31 March 1998, the staff complement has increased to 322 officials, 234 of whom are already in appointment (88 in Ireland). The remainder are either in the course of being appointed or will arrive over the coming months.

A final allocation of 18 posts should be received in the 1999 budget to bring the staff to its designated level of around 350 officials (170 in Ireland)

3.3 Legal Matters

In this area, activity during the reporting period focussed on the following issues :

- Control of Transposition and Application of Community Legislation
- Meetings of Senior Consumer Policy Officials from the Member States
- Enlargement
- Enforcement
- Access to Justice Action Plan
- CLAB Database
- Studies and Pilot Projects

3.3.1 Control of Transposition and Application of Community Legislation

DG XXIV is in charge of controlling the implementation in the Member States of Community legislation in the field of consumer protection. Last year, work in this area focussed on the directives on timeshares, unfair contractual terms, package travel and consumer credit.

Directive 94/47 (timeshares) came into force in April 1997. As yet, only nine Member States have transposed this directive into domestic legislation. "Reasoned Opinion" letters have been dispatched to the Member States that have not transposed the directive. The transposing laws were monitored and, where appropriate, infringement procedures for non-conformity will be initiated.

The transposition of Directive 93/13 (unfair contractual terms) by the Member States is also giving rise to a great number of infringement procedures for non-conformity.

With regard to Directive 90/314 (package travel), three infringement procedures for non-conformity are pending and a further procedure will probably be opened soon.

Due to recent changes in Community legislation on price indication, infringement procedures pending in that field have been closed. The legislation of Member States will be monitored in the light of the new Directive 98/6/EC of the European Parliament and the Council of 16 February 1998 on "Consumer protection in the indication of the prices of products offered to consumers".

In addition, Unit C2 is constantly involved in receiving and answering complaints (averaging three per week) from individuals. Many of these complaints refer to unsatisfactory experiences with professionals or traders, but as the Commission has no competence in the field of disputes between private individuals, these complaints cannot be dealt with. In such cases, DG XXIV tries to provide helpful information to the complainant and to direct him to the relevant governmental or non-governmental body.

Other complaints regarding the violation of Community legislation by a Member State induced the Commission to initiate infringement procedures.

3.3.2 Meetings of Senior Officials

The tradition of convening senior officials responsible for consumer policy at national level has been suspended in recent years. To revive this tradition, a meeting chaired by the Director-General of DG XXIV took place in March 1997 and was warmly welcomed by Member States. In fact, Member States showed interest in developing closer co-operation with the Commission through the periodical organisation of such meetings. Therefore another meeting chaired by the Director-General took place on 13 January 1998 to meet this demand and to develop a more systematic approach for the future. The main points of the meeting were the recent developments in European consumer policy, food safety, the introduction of the Euro, enforcement of consumer legislation, as well as access to justice and the implementation of its respective action plan.

As Member States reiterated their interest in holding this kind of meeting, the Director-General proposed organising meetings every six months at the beginning of each Presidency.

3.3.3 Enlargement

One of the priorities for consumer policy in 1997 was to assist Central and Eastern European Countries (CEECs) in developing consumer policies. This action is carried out under specific multi-country PHARE programmes on Consumer Policy and PHARE programmes related to each country, by means of European agreements with CEECs, participation in the activities of TAIEX (Technical Assistance Information Exchange Office), participation in the preparatory work on pre-accession and by bilateral contacts.

DG XXIV has collated all the information on the development of consumer policy with a view, in particular, to monitoring the implementation of consumer directives in these countries and to providing some guidelines and political inputs. It has contributed to the drafting of accession partnerships concluded with each of the applicant countries, setting out priorities in the field of consumer policy and health protection and has continued to assess their situation and their problems in these areas.

In order to achieve an effective consumer policy in the CEECs, the European Commission has recently signed a contract of 2 Mio ECU for the implementation of a new PHARE programme – Consumer Institutions and Consumer Policy – in thirteen PHARE countries. DG XXIV was instrumental in the elaboration of this programme and has been involved in its implementation which started in March 1998.

TAIEX helps the CEECs in their preparation for integration into the Single Market. DG XXIV cooperates with TAIEX in order to organise consumer protection activities. In the past year, DG XXIV was involved in the organisation of TAIEX

external workshops with experts from Member States and CEECs in Latvia, Bulgaria and Slovakia.

Multi-country workshops for experts from all CEECs took place in Brussels in October 1997 and March 1998.

3.3.4 Enforcement

Following a specific request made by the UK Presidency, DG XXIV submitted in late 1997 a non-paper on enforcement of European consumer legislation which was discussed at the meeting of senior officials on 13 January this year and was favourably received.

On the basis of this non-paper and contributions from the Member States, a working paper on enforcement of European consumer legislation was drafted by DG XXIV and adopted by the Commission on 27 March 1998.

The paper gives a broad picture of the situation, highlighting complexities and difficulties, summarising initiatives taken at European and national level, and, finally, presenting some ideas for improvement. It aims at improving the transparency of enforcement arrangements in the Member States, strengthening co-operation and co-ordination between the different enforcement authorities and between these authorities and the Commission.

3.3.5 "Access to Justice" - Action Plan

During 1997, DG XXIV continued consultations on the "Access to Justice" action plan of 1996. Following these consultations, DG XXIV drafted a new communication on the out-of-court settlement of transborder consumer disputes which underwent a new consultation procedure and was discussed with experts from the Member States in two meetings, in December 1997 and February 1998. The Commission adopted the final version of this document on 31 March 1998.

In this Communication two initiatives are planned:

- a Recommendation establishing criteria for the creation and the functioning of out-of-court procedures applicable to consumer disputes,
- a standard European claim-form for consumer disputes to improve the dialogue between consumers and professionals in order to reach – as far as possible – an amicable solution.

The form will be available in all the official languages of the European Union (<http://europa.eu.int/comm/dg24>).

3.3.6 CLAB Europa

DG XXIV has made publicly available a new database called "CLAB (Clauses Abusives) Europa" on case law with regard to unfair terms in consumer contracts in the European Economic Area (EEA) countries (<http://europa.eu.int/comm/dg24>).

In more than 5 000 files, CLAB Europa provides information about contract terms considered to be unfair within the different Member States of the European Union.

The database covers all Member States of the Union, as well as Norway and Iceland (members of EEA) and is continually updated.

All texts included in the database appear in their original version as well as in French and English.

3.3.7 Studies and Pilot Projects

In 1997, two research projects have been completed :

- "Application of Directive 93/13 to Contracts in Public Services" by the *Institut national de la consommation* in Paris;
- "Bibliography of Consumer Protection Law" by the *Université Catholique de Louvain*.

Both will be available on the Internet.

3.4 Development of Consumer Information and Representation

One of the main horizontal tasks of DG XXIV is to increase consumer awareness by information and education. A variety of actions was launched with the aim of informing both a general and specialised public as efficiently as possible.

DG XXIV's central *Information Campaign* in 1997 focussed on "unfair contractual terms" and was staged in the general framework of the Commission's "Citizens First" action which aims at informing the public about the achievements of the Internal Market. Five Member States (Greece, Italy, Spain, Portugal and Ireland) with a less developed consumer representation structure were singled out for this specific campaign. Their respective national consumer organisations participated in the practical information actions, particularly those dealing with consumer sensitive questions such as "Buying goods and services in the EU" and "Travel within the EU".

After an evaluation study in 1997, the "*Euroguichets*" which have been in existence since 1991 have undergone quite a significant change, both in terms of their number and mission. Of the 17 Euroguichets financially supported by the Commission in 1996, only 10 will continue to receive funding. Their scope and field of action will be brought into line with other projects funded by the EU. The prime task of the remaining 10 organisations will be shifted from "transborder problem-solving" to supplying the whole of their respective Member States with pro-active information on consumer affairs.

DG XXIV's own communication vehicle, "*Info-C*", a bi-monthly magazine on various consumer matters continued to be published – in growing numbers – in 3 languages. Currently a total of 11 000 copies are distributed in 90 countries (of which 8 000 copies in the Member States and 3 000 copies in non-member countries).

In response to the European Parliament's no-confidence motion and the Commission's commitment to reform and transparency, it was decided to open up a new section on the DG XXIV homepage to the activities of the reformed scientific committees and the newly created Food and Veterinary Office (FVO) in Dublin. This page provides full details about the mandate, agenda, structure and results of the discussions

of each of the scientific committees. The page was opened in May 1997 and has since then also carried the full reports of the inspections and audits of the FVO (in both cases, however, business secrets were exempted from publication).

At the beginning of November, Commissioner Bonino hosted an *Internet "Chat-line"*. During the two-hour international question-time, during which, at any one time, around 125 persons were connected, she personally answered some 300 questions on health, food-safety and consumer topics.

During 1997, DG XXIV's consultative body, the *Consumer Committee*, met four times and, in particular, pronounced opinions on current consumer-sensitive issues such as the "Euro" and the Commission's Green Paper on the "General Principles of Food Law in the EU". The respective working-groups discussed the safeguarding of consumer interests, particularly as regards financial services and the introduction of the new EU-wide currency.

In July 1997, a special *conference* was held in Brussels for 45 *consumer organisations* from the five Member States in which the 1997 campaign (see above) was conducted and in which consumer information is less developed and widespread. The aim was to provide information on topics of consumer concern and to enhance these countries' ability to take part in the work concerning consumer protection at European level.

Consumer Education and Training

Following the Council Resolution on Consumer Education and Information, adopted in November 1995, DG XXIV sent a questionnaire to Member States in 1996 with the aim of identifying the extent of their current efforts to promote consumer education in primary and secondary schools.

The answers provided the key elements for a working document of the Commission presented by Mrs Bonino to the Consumer Council in April 1996.

DG XXIV has endeavoured to establish regular links with other Directorates-General responsible for *education and training*. The aim is to fully exploit the possibilities offered under existing Community programmes and initiatives, as well as to ensure that consumer education and training is a major complement to the wider objectives of encouraging socio-professional integration of youngsters and adults.

An example of such a *synergy* between DG XXIV and the European Social Fund (DG V) is the successful continuation of two pilot projects aiming at integrating consumer education in the national school curricula. The first one started in Greece in 1996; the second one will be launched in Portugal in 1998.

The "*Young Consumers' Competition '97*" organized by DG XXIV with a view to mobilising the interest of European youths in consumer-related issues, prompted refreshing and interesting ideas. Prizes for producing a "Young Consumers' Magazine" on issues of particular interest to that age-group

(e.g. pocket money, "green consumption", advertising, the euro etc.) went to a college in France (1st prize), a college in Ireland (2nd prize) and a college in Denmark (3rd prize), with tributes paid to numerous other interesting contributions from schools in the rest of the Member States.

3.5 Relations with The Other Institutions

Another major responsibility of DG XXIV is the coordination of relations between the Commission and the European Parliament, the Council and the other institutions as well as liaison with the Food and Veterinary Office in Dublin.

During the period concerned, a number of important dossiers were examined in the different institutions ranging from directives on consumer credit, injunctions and guarantees to the follow-up work in the European Parliament on the BSE enquiry report.

3.6 Liaison with The Food and Veterinary Office

The main activities of the liaison section have been to develop and maintain links between the FVO and other parts of DG XXIV, other DGs and other institutions.

The main links have been developed with DG VI in relation to the forwarding of reports, draft proposals for Commission Decisions, participation in meetings, such as the Standing Veterinary Committee, and specific legislative working groups (controls, simplification etc.). Contacts have also been developed with DG I in relation to the results and follow-up of FVO missions.

The liaison section has also been involved in meetings likely to have an impact on FVO activities (equivalency agreement discussions, Chief Veterinary Officers' meetings). It has also been involved, in conjunction with the FVO, in the development of mission programmes (mission prioritisation, methodology and audit).

The liaison section also provides DG XXIV with advice on various subjects and takes part in meetings with Member States or third-country representatives, e.g. in relation to discussions concerning fishery-product exports from Madagascar or the residues-monitoring issue in the USA. It has also contributed to the elaboration of the different drafts of Commission Communications and Reports to the European Parliament and makes a regular input to replies to the European Parliament's written questions.

Two proposals for Commission Decisions relating to the checks carried out by the FVO in Member States and in third countries have been drafted by the Liaison Section. They were adopted by the Commission in February.

3.7 Relations with Third Countries

The growing importance of the representation of consumers' interests within the EU is clearly reflected in the Commission's efforts to incorporate the consumer dimension in development policy and in the policies of countries with economies in transition.

3.7.1 Developing Countries

Consumer policy and consumer health protection were included in the Communication of the Commission on the future relations with the ACP countries. This means that consumer policy will, for the first time, be part of the future "Lomé IV bis" agreement. In this context, an important pilot project on access to water was adopted for Senegal (Dakar). The provision of fresh water is a severe problem which people have to face when living in conurbations where health defects and overcrowding are common. The absence of running water in privacy and the joint use of sanitary equipment expose consumers to

contamination or microbial infections. The whole project, which aims at providing people in three Dakar slum areas with access to healthy fresh water, is being run by local consumer organisations.

3.7.2 TACIS

Two significant consumer projects were adopted, one for Russia and the other for the Ukraine. Their purpose is not only to promote consumer policy but also civil society.

Both projects are carried out under long-term technical assistance schemes, to help the beneficiaries – important consumer organisations – improve their professional profile and work, as well as to enter into contact, with their European counterparts.

The duration of these projects is two years.

3.7.3 Agreements with Third Countries

At the moment, there are as many as 19 agreements with a consumer policy clause. Co-operation ranges from general information exchange to harmonisation of legislation.

4. ● Food and Veterinary Office ●

In parallel with the concern to re-establish consumer confidence, particularly in the wake of the BSE crisis, the Food and Veterinary Office was set up in Dublin.

Its aim is to monitor and audit Member States' responsibilities for implementing EU legislation on food safety, animal and plant health as well as animal welfare. The central issue has certainly been to enhance consumer confidence with regard to food safety measures.

4.1 Role and Functions of the Food and Veterinary Office

4.1.1 Mission of the Food and Veterinary Office

The Food and Veterinary Office was established on 1 April 1997 when it became part of the Directorate-General for Consumer Policy and Consumer Health Protection. Prior to then, it had been known as the Office for Veterinary and Phytosanitary Inspection and Control and was attached to the Commission's Directorate-General for Agriculture.

The Office's principal mission is :

- to monitor the observance of food hygiene, 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.

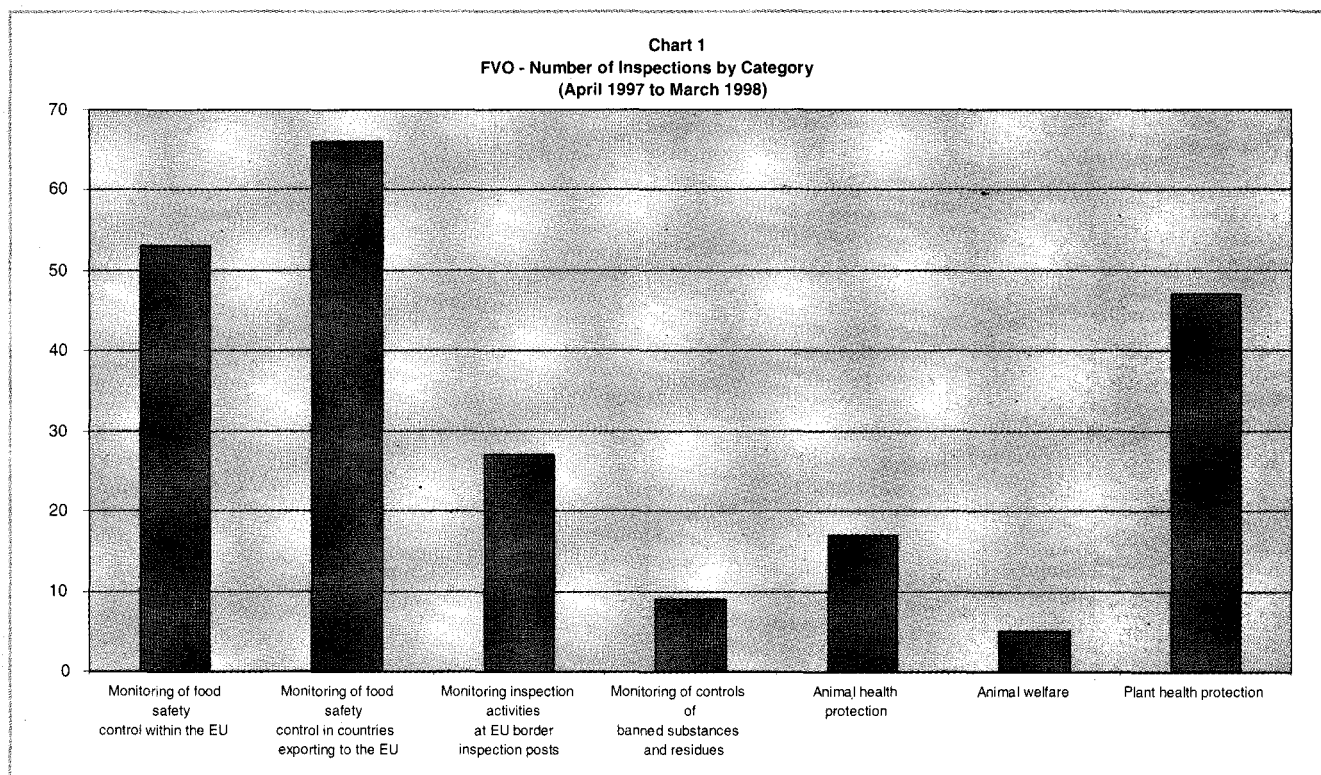
It fulfils its mission by carrying out a programme of inspections to monitor the performance of competent authorities, including on-the-spot inspections of individual establishments in both Member States and third countries. The main fields covered by this programme are the following :

- Food Safety within the EU
- Food Safety in Third Countries Supplying Food to the EU
- EU Border Inspection Posts
- Banned Substances and Residues
- Animal Health Protection
- Animal Welfare
- Plant Health Protection.

In its first year of operation the Office completed around 200 inspections.

In this report, the inspections carried out within the European Union are dealt with in section 2, those relating to non-EU countries are covered in section 3 while those relating to plant health protection (both EU and non-EU) are dealt with in section 4.

Chart 1 below summarises how the inspection activities of the FVO were organised in 1997:



Three main principles have guided the development of the Office's activities during its first year:

- *Independence:* The ability of the Office to carry out its duties and to present its findings free from external influence has been given the highest priority.
- *Transparency:* The need for the Office's activities to be open and transparent has always been to the forefront.
- *Excellence:* The Commission has given a commitment that the Office will be fully resourced and that its management and working methods will be based on the most up-to-date principles.

4.1.2 Resources and Organisation

During 1997, the Office embarked on a number of major initiatives aimed at enhancing its overall efficiency and effectiveness. These included:

- the development of an inspection prioritisation methodology;
- the gradual expansion of the inspection activities to cover the whole food production chain;
- the introduction of an audit approach to assessing food control systems operated by Member States and third countries to complement on-the-spot checks of individual establishments;
- the development of a manual of operations in order to define transparent and standardised procedures for preparing, carrying out and reporting on inspections.

The overall goal has been to develop a harmonised approach to control and inspection activities for all parts of the food

production chain based upon the careful targeting of inspection and control resources.

On its establishment on 1 April 1997, the Office had a total of 75 posts. The Commission has set an overall target of 202 posts for the Office, of which at least 60% will be inspection staff. During the past year, intensive efforts have been made by the Commission, supported by the European Parliament and the Council, to move towards this target. By 31 March 1998 the Office had a total of 150 posts.

A series of competitions was held during 1997-98 to establish panels of suitably qualified experts in food safety, animal health, plant health and animal welfare from which vacant posts in the Office will be filled.

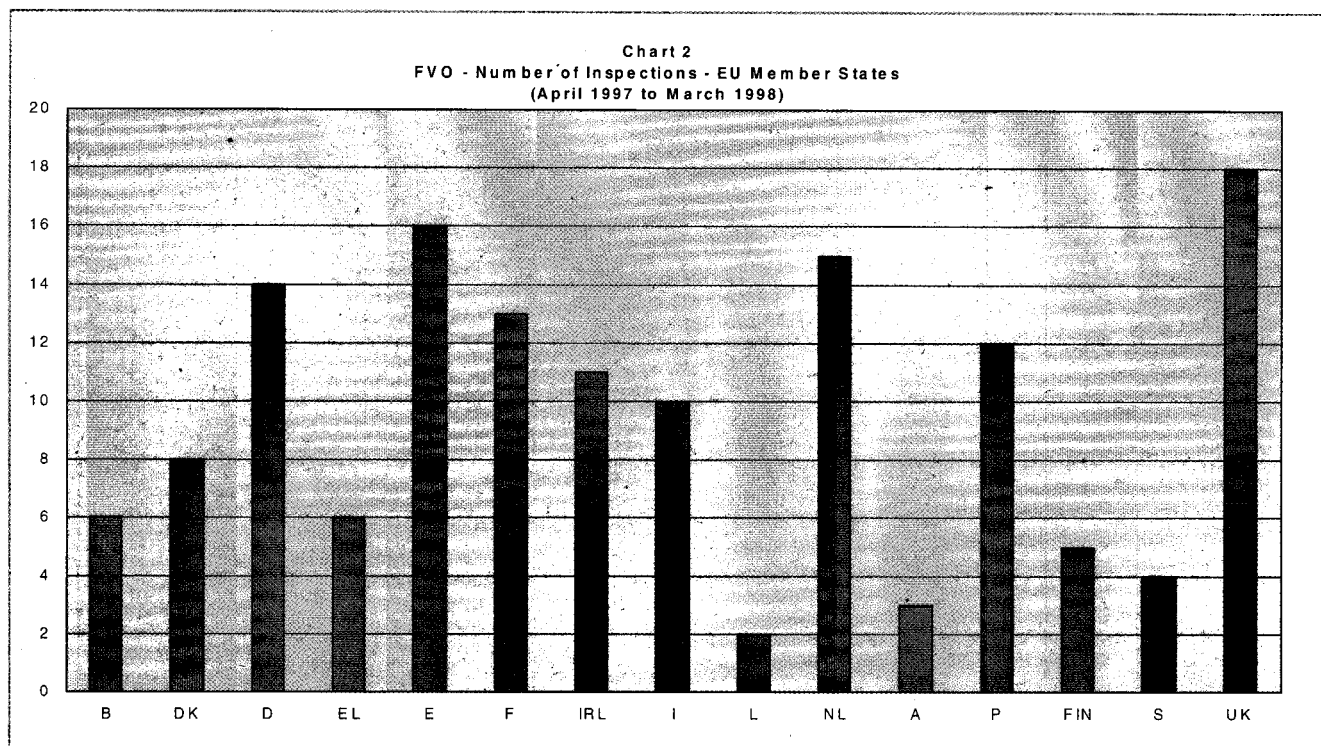
In October 1993, the European Council agreed to relocate to Ireland what was then known as the Office for Veterinary and Phytosanitary Inspection and Control. This decision came into effect when the Office established its headquarters in temporary offices in Dublin on 1 September 1997. By 31 March 1998 a total of 52 staff had been appointed to the Office in Dublin and moves were underway to appoint a further 70 or so staff by the end of 1998.

The Office is organised in five inter-related management units (three inspection units and an administration section based in Ireland, as well as a liaison section based in Brussels) to ensure effective liaison between the Office and other Commission services, other Community Institutions and outside bodies. The Office also has inspectors based in the Commission's delegations in Washington and in Budapest. Generally, experts from Member States accompany and assist the Office's staff in carrying out inspections. In 1997, such experts took part in over one hundred inspections undertaken by the Office.

4.2 Inspections Programme in EU Countries

4.2.1 Monitoring of Food Safety Controls

The following chart gives a breakdown of inspections in the Member States carried out during the period covered by the report:



The inspection activities of the FVO within the EU in 1997 were dominated by the continuing BSE crisis.

Since 1 April 1997, the FVO has undertaken 40 inspection missions with regard to bovine spongiform encephalopathy (BSE). Most of these inspections dealt with the implementation of the new EU-standards for the production of meat and bone meal and the ban on feeding mammalian meat and bone meal to ruminants. The missions revealed that the new rendering standard, decided upon with a view to the inactivation of the BSE agent, was fully implemented in only one Member State. Nevertheless, considerable efforts were made by the industry and the authorities towards compliance with the relevant Commission Decision.

A second priority has been inspections in the United Kingdom. They have covered, in particular, compliance with the export ban for beef and beef products and the derogation from this ban as foreseen by Community rules. With their recommendations, the FVO inspectors contributed to major improvements in the controls undertaken by the UK authorities and to changes in Community legislation approved in March 1998, laying down stricter control provisions.

One further priority was the monitoring of progress made in the UK towards a step-by-step lifting of the export ban. The fulfilment of the preconditions, and the rules for the first step of this lifting, were assessed by FVO inspectors.

In this context, the FVO made a significant contribution in the detection of international links in the fraudulent export of beef from the United Kingdom.

The missions carried out in this context demonstrated the need for improvements in the system of controls of intra-Community meat trade and closer collaboration between the competent authorities of Member States and the responsible Commission services.

Apart from the issue of BSE, three other main activities were undertaken by the Office in 1997 in relation to food safety control within the EU concerning fresh meat, meat products and fish/fishery products.

Inspections in 1996 had revealed a number of major deficiencies in control systems relating to *fresh meat* establishments in several Member States. In 1997, follow-up inspections were carried out in Germany, Spain, France, Ireland and Luxembourg to assess whether these deficiencies had been corrected. While considerable improvements were observed, some establishments were still considered to present potential health risks (in Spain, France, Ireland, Germany and Luxembourg). Infringement proceedings were therefore initiated by the Commission.

A major inspection effort had also been carried out in 1995/96 covering a sample of 10% of establishments in the EU producing *meat products*. During 1997, a detailed analysis of the results of these inspections was carried out, on the basis of which a report will be presented to the Standing Veterinary Committee before mid-1998.

A similar inspection effort was completed for *fish and fish products*, with the last inspections taking place in Germany and Portugal in 1997.

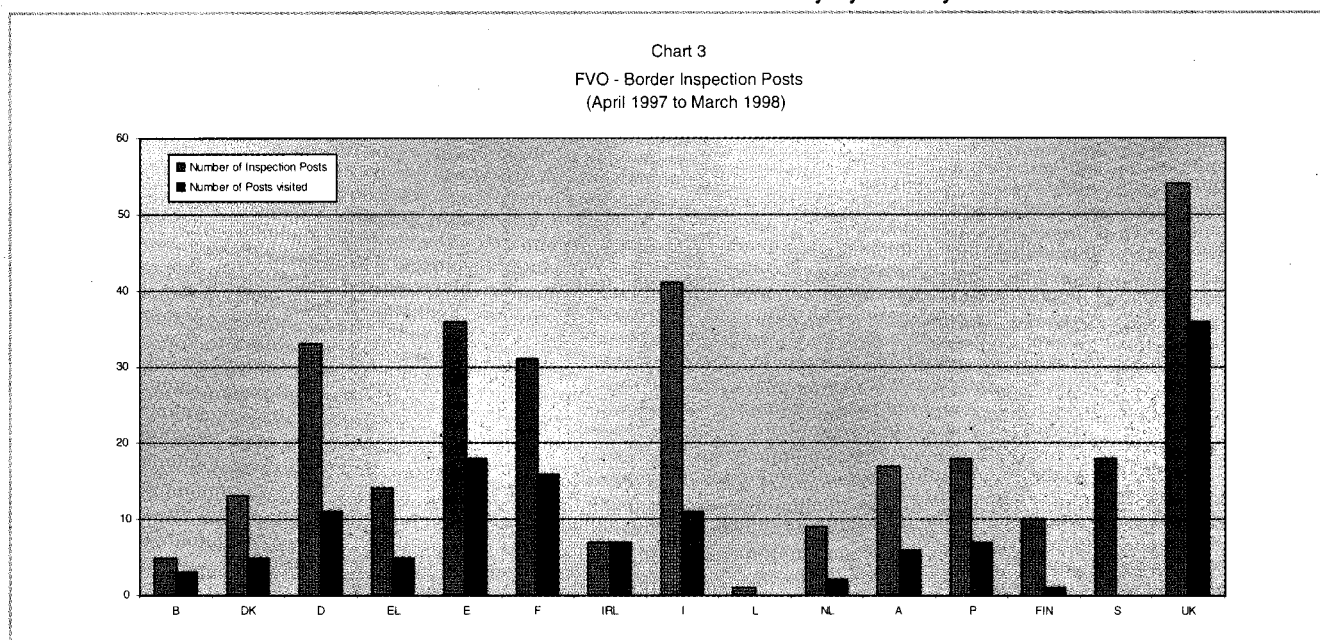
4.2.2 Border Inspection Posts (BIP)

EU legislation requires that major BIPs (more than 2 000 consignments per year) be inspected annually and smaller BIPs (less than 2 000 consignments) be inspected every three years. The FVO has not been able to meet this requirement in 1997 due to limited staff resources. Nonetheless, some thirty missions were undertaken covering 127 border inspection posts.

pose of these inspections was to assess the systems of control of residues and of the sale and distribution of veterinary medicines operated by the Member States. Several inspections of reference laboratories were also undertaken.

The inspections indicated that Member States are somewhat slow in putting into effect the two basic EU Directives adopted in 1996. Inadequate staffing and equipment is a feature of national control systems which reflects the low priority given by some Member States to this activity.

Chart 3 indicates these activities country by country.



However, there are major variations between BIPs in the relative volumes of throughput of imports. For example, Rotterdam in the Netherlands is Europe's largest port and has a throughput many times greater than the average BIP. It should also be noted that the figures in the above chart cover veterinary/animal health inspections only, as there is currently no legal requirement for B.I.P. inspections relating to plant health.

The major facts observed during these inspections in Member States were:

- substantial progress in the development of infrastructure and equipment in most BIPs. However, in some border inspection posts the situation was critical and deadlines for improvement were set;
- the need for staff to be reinforced and the opening hours increased to respect animal welfare requirements;
- procedures concerning notification, checks and application of the requirements of Annex B to Directive 72/462/EEC needed to be improved, especially concerning warehouses and free zones;
- there was inadequate communication between BIPs mainly due to the absence of the system for the health control of imports from third countries at frontier inspection ports (SHIFT).

4.2.3 Control of Residues and Banned Substances

Following the adoption of Council Directives 96/22/EC and 96/23/EC, the FVO organised five major inspections in 1997 in Spain, Greece, Italy, Germany and Ireland. The pur-

4.2.4 Animal Health Protection

The Food and Veterinary Office monitored the evolution of the outbreak of classical swine fever which had developed in Europe from January 1997. Germany, the Netherlands and Spain were particularly affected. Eleven inspections were carried out during the period of the report. The primary objective of these inspections was to verify the implementation of control measures foreseen in Directive 80/217/EEC and, where appropriate, to assist the competent authorities in their fight against this disease.

In the majority of cases observed, Directive 80/217/EEC was correctly implemented. The Office nevertheless noted some shortcomings in regard to the conduct of epidemiological enquiries.

In zones where there is a high density of pigs, the fight against the disease had to confront specific constraints such as control of transport, reproduction related problems, market measures, availability of trained personnel and their level of experience, slaughtering capacities and rendering capacities. These aspects were shown to be of primary importance in the evolution of the disease in the Member States concerned.

The regular appearance of outbreaks in Germany poses the problem of the persistence of the disease in wild swine and the adequacy of control and eradication measures.

4.2.5 Animal Welfare

In the field of animal welfare, the FVO continued to carry out visits in the Member States and in two third countries. Efforts were concentrated mainly on animals during transport (Council Directive 91/628/EEC on the Protection of Animals during Transport).

The most important shortcomings found were in vehicles and vessels used for transport. Animals being transported over long distances were often not rested, watered, fed and unloaded as required, whilst route plans were not always available. Carelessness and indifference to animals were still found, in particular on board vessels during transport.

In certain Member States, significant deficiencies were observed in markets with regard to mishandling of animals during unloading/loading, during driving of animals by drovers and cattle which were tied so that they could not lie down. In some BIPs, where livestock including horses arrive, the competent authorities failed to provide adequate rest periods for the animals.

Although there are still certain deficiencies noted in the application of Directive 93/119/EEC, in particular as regards the stunning and bleeding of animals at the time of slaughter, the overall situation appears to be improving.

4.3 Inspections Programme in Third Countries

The Office’s inspection activity under this heading is described according to the following main regions of the world:

EFTA	Africa
Central & Eastern Europe	Far East
North America	Middle East
Central & South America	Oceania

4.3.1 EFTA (Norway, Iceland, Liechtenstein and Switzerland)

The EU maintains a close working relationship with EFTA countries. Under the European Economic Area agreement which came into effect on 1 January 1994, EFTA and EU countries have agreed to apply uniform rules and regulations regarding the single market on food safety, animal health, animal welfare and plant health.

Under this agreement, EFTA have set up their own Surveillance Authority to carry out inspections in their own countries to control food safety. This is the main reason why FVO inspections are very limited in this area.

There is close collaboration between the relevant inspection services in preparing inspection programmes. In some cases, staff from the inspection services participate in joint inspections of mutual interest and in certain internal working groups.

As observers at meetings of the Standing Veterinary Committee, representatives of EFTA receive all inspection reports submitted by the Office to the Committee.

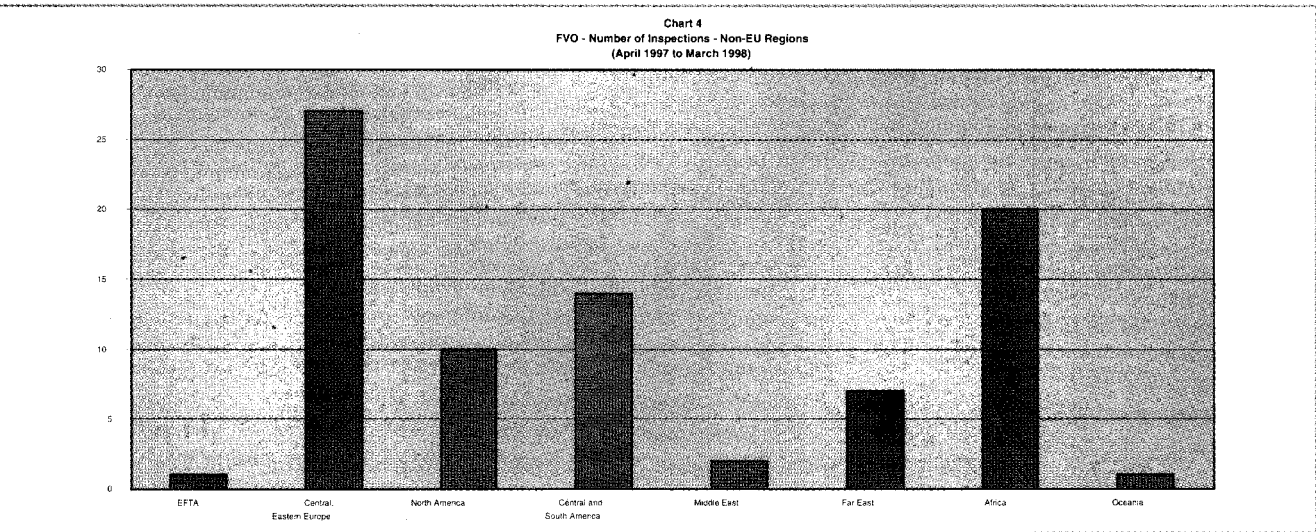
4.3.2 Central and Eastern Europe

During 1997, the Office carried out a wide range of inspections in Central and Eastern Europe. These can be classified broadly under the following headings:

- milk and milk products (Croatia, Bulgaria, Poland, Romania, Estonia, Latvia)
- meat and meat products (Poland)
- general audits of food safety control systems (Poland, Romania, Bulgaria, Croatia)
- animal health (Czech Republic, Poland, Romania, Croatia, Hungary)
- fish products (Croatia)
- egg products (Czech Republic). This inspection was carried out following a “Rapid Alert System” notification concerning the detection of salmonella in these products.

For some countries, such as the Czech Republic, Hungary, Poland (in the case of meat and meat products) and Croatia, the overall performance of animal health control services was

Chart 4 outlines the inspection programme according to these regions:



considered to be adequate, although improvements in certain areas were recommended and some establishments were removed from approved lists. However, for Bulgaria, serious deficiencies existed which called for a suspension of all imports of milk products and the continuation of imports only from certain regions of Bulgaria. For Poland, on the basis of the outcome of the inspections on milk and milk products, the duration of the list of dairy establishments has not been prolonged. Control systems in Romania were considered capable of meeting EU requirements, but some concerns remain.

An inspection was carried out in the former Republic of Yugoslavia. Foot and mouth disease and classical swine fever are still serious risks there, but the Office recommended that part of the country could be approved for export of some meat (excluding pig meat for human consumption) and meat products to the EU under strict conditions.

There are serious animal health concerns for the whole Balkan area as regards foot and mouth disease, particularly as there is a "type A Iran strain" in Turkey against which there is no suitable vaccine cover in the Community.

A request from Estonia to be included on the list of approved countries for export of milk and milk products was refused pending improvements in the system of control of milk products and production plants.

The Office's staff have participated in a number of seminars either organised by the EU or with EU financial assistance, for inspection services in the countries of Central and Eastern Europe. The Office also participated in the negotiation of the Equivalency Agreement concluded with the Czech Republic and in the ongoing discussions with Hungary, Poland and the Slovak Republic.

4.3.3 North America (Canada, Mexico, USA)

The FVO's activities in this region during 1997 fell into the following broad categories:

- on-the-spot checks in the USA, Canada and Mexico mainly concerned establishments producing meat and poultry for the EU market. Major problems were identified during these inspections in relation to the poultry plants in the USA which led to the suspension of all poultry exports to the EU;
- an inspection concerning the residue control system was carried out in the USA; the inspection found that major improvements were required in order to be able to consider the system equivalent to that of the EC;
- fish and fish products – only Mexico was inspected and no significant problems were found.

In September 1997, staff of the Office accompanied an inspection team from the United States' Food and Drugs Administration which carried out an evaluation of safety controls of fish production in several EU Member States. In March 1998, staff from the Office also accompanied an inspection team from the US Department of Agriculture which carried out an evaluation of residue controls in several EU Member States. In July 1997, staff accompanied the US Department of FSIS (Food Safety Inspection Service) to France to carry out a four-week public health inspection at selected French establishments.

Staff of the Office also participated in the negotiation of the EU-US Equivalence Agreement.

4.3.4 Central and South America

Inspections were carried out in Argentina, Costa Rica, Honduras, Uruguay, Colombia, Peru, Paraguay, Brazil, Chile, Falkland Islands, Guatemala, Venezuela and Ecuador.

These concentrated mainly on assessing requests by countries to be included, or to have part of their territory included, in approved lists for meat and certain meat products and for fish and fish products. On-the-spot checks were also carried out in establishments in some of the countries which had already been provisionally approved as meeting EU food safety standards or were seeking initial approval. In general most requests were approved.

During the mission in Argentina, the residue control system was re-evaluated.

However, some deficiencies were identified:

- Findings in Argentina regarding the procedure for establishment pre-listing (i.e. provisional listing prior to an inspection) led the FVO to recommend temporary suspension of this procedure.
- Brazil, Venezuela, Colombia, Ecuador and Peru have been provisionally approved since 1992 for the re-importation of EU horses into the EU. Inspections of the control systems in these countries sometimes showed significant weaknesses which needed to be urgently addressed.
- Some states in Brazil, proposed for exporting certain meats, did not meet EU animal health requirements and were therefore not included in the lists of approved regions in that country.

Staff of the Office also participated in the negotiations of Equivalence Agreements with Argentina, Chile and Uruguay.

4.3.5 Africa

Inspections in Africa during 1997 were concerned mainly with the assessment of requests from countries to be included in, or remain on, lists of countries approved for exporting fish and fish products to the EU (Nigeria, Ghana, Tanzania, Uganda, Kenya). Deficiencies in control systems were identified by the FVO and approval was delayed or withheld pending guarantees concerning corrective action for the last 3 countries. For Nigeria and Ghana, it was the first evaluation mission and, after receiving certain guarantees, these 2 countries were proposed for addition to List I of Commission Decision 97/296/EEC.

Madagascar was visited both for fishery products and animal products. Serious deficiencies were found in relation to the disease situation and veterinary controls and, as a result, a ban on imports was imposed. Following a subsequent FVO inspection in Madagascar in October 1997, and receipt of additional guarantees, only the ban on fishery products was lifted in November 1997.

An inspection in Zimbabwe concerned very different issues such as beef, ostrich, and fish imports and assessment of crocodile meat production. Some serious animal and/or public health problems in relation to these imports have not yet been solved – for example, conditions relating to welfare of crocodiles at slaughter and animal health import conditions.

4.3.6 Far East

The main FVO activity in this region in 1997 related to fish and fishery products (China, Bangladesh, India, Philippines, Pakistan), poultry (China) and horses (Turkmenistan).

The Commission imposed a ban on fish and fishery products from India and Bangladesh from 1 August 1997, following FVO inspections which identified serious weaknesses in control systems. Following a subsequent FVO inspection in Bangladesh in December 1997, and receipt of written guarantees from the Bangladesh authorities, the ban was lifted in February 1998 and a number of establishments cleared for export of products to the EU. An FVO inspection in India in November 1997 also recommended the lifting of the ban and this took effect from December 1997.

An inspection in the Philippines concluded that this country did not meet the standards required for export of live bivalve molluscs to the EU; furthermore, the list of establishments approved for exporting fish and fishery products to the EU was reduced. Guarantees concerning corrective action were received.

A major FVO inspection took place in China in July 1997 to consider whether that country could be included in lists of countries approved for export to the EU of poultry meat, fish products, bivalve molluscs, casings and rabbit meat. Although significant progress was noted for certain issues, some further improvements, especially on poultry and bivalve molluscs, were considered necessary.

Turkmenistan had applied for the export of certain breeds of horses to the EU but this application was rejected following an FVO inspection which concluded that local animal health controls were inadequate.

4.3.7 Middle East

There were relatively few FVO inspections in this region in 1997. The most significant was concerned with imports of horses from Turkey (which had been given provisional clearance in 1997) and for fishery products. Following the inspection, a ban was imposed on all imports of horses from Turkey since the Office concluded that there were serious deficiencies in animal health control systems and, for fishery products, certain restrictive measures concerning shellfish and fresh fish have been taken.

4.3.8 Oceania

A visit was carried out in Australia to verify whether the EU requirements concerning the importation of fresh meat were being complied with. The FVO team assessed the Central Competent Authorities (CCA) and visited establishments producing fresh meat. The mission was designed to examine the performance of the competent authority.

It was concluded that the veterinary supervision in Australia, as influenced by the policy of the CCA, could not ensure

that all requirements of EU legislation are met. Moreover, it could not be excluded that the supervision and certification arrangements might lead to serious problems with consequences for public health.

Provided that the CCA undertook to correct the system and establishment deficiencies throughout Australia in order to comply with EU requirements, the FVO recommended the list of approved establishments could possibly be maintained for a period of six months with a verification re-visit.

4.4 Plant Health Protection

Council Directive 77/93/EEC sets the goal for preventing the introduction into the EU of organisms harmful to plants and plant products (PPPs) or their spread within the EU. One of the Food and Veterinary Office's main functions is to supervise the way plant health controls for PPPs originating in the EU or imported from third countries are carried out by the Member States.

4.4.1 Protected Zones

Protected zones (PZ) have been designated within the EU to take account of differing pest and disease situations and different crop and growing conditions. Such zones exposed to particular plant health risks have been defined and accorded special protection. During 1997, the Office carried out inspections on zones in:

- Ireland on *Erwinia amylovora*
- Italy on *Erwinia amylovora* and *Citrus Tristeza Virus* (CTV)
- France (Brittany) on *Beet Necrotic Yellow Vein Virus* (BNYVV)
- Denmark on *Bemisia tabaci*, *Tomato Spotted Wilt Virus* (TSWV) and BNYVV
- Portugal with respect to CTV

4.4.2 Local Movement (exemption from plant passport requirement)

Since the establishment of the Single Market, plant passports are used for trade within the EU to replace the phytosanitary certificate. Under certain conditions, producers may be exempted from the passport requirements, the so-called "local movement". A questionnaire on local movement was sent to the Member States. Based on the replies, missions were carried out to Denmark, United Kingdom and Spain. Future missions are planned to other Member States that apply local movement.

4.4.3 Outbreaks and/or Control of Harmful Organisms on Plants and Plant Products

Inspections were carried out on the measures undertaken by:

- the United Kingdom on an outbreak of *Dendroctonus micans* and of *Pissodes* spp. in forests and on conifers in the PZ.
- Spain on an outbreak of a new insect in the EU *Rhynchophorus ferrugineus* on plants of Palmae.
- the Netherlands on the control of *Thrips palmi* (Commission Decision 96/702/EC).

- Portugal to assess the damage of a TSWV outbreak on tomato plants in the South.
- Denmark to assess the damage of outbreaks of TSWV on several plant species and *B. tabaci* on plants of *Euphorbia pulcherrima* in the PZ.
- Ireland on an outbreak of *Pissodes* spp on *Pinus* spp in the PZ.

4.4.4 Derogations

Under EU legislation, a derogation may be granted to Member States to import, under strict conditions, certain plants and plant products that are normally prohibited. The Office conducted a number of inspections in 1997 to monitor the application of these derogations:

- Italy - on strawberry plants from Argentina.
- UK - on strawberry plants from South Africa
- UK - on oak logs from the US
- Portugal and Italy - on seed potatoes from Canada.
- Argentina - on strawberry plants

Potatoes are an important part of the diet of the European consumer. Strict controls are applied on potato diseases and pests that have potentially important economic consequences. Two diseases caused by bacteria are important: "ring rot" caused by *Clavibacter michiganensis* ssp. *sepedonicus* and "brown rot" caused by *Pseudomonas solanacearum*. An important part of the Office's activities in 1997 was to monitor the controls of these two diseases.

Inspections on "brown rot" were carried out in:

- The United Kingdom - on potatoes originating from Egypt
- Portugal, Spain and Germany - on measures taken after outbreaks in 1996 and 1997
- The Netherlands - on the implementation of Commission Decision 95/506/EC
- Egypt - on measures laid down in Commission Decisions 96/301/EC and 98/105/EC

Inspections relating to "ring rot" were carried out in:

- Denmark - in relation to infected potatoes originating from Denmark that were detected in Sweden, and on the implementation of Directive 93/85/EC.
- France - to assess measures put in place to eradicate an outbreak.
- Germany - after official notification of several outbreaks of the disease.
- Sweden, Finland and Portugal - on the implementation of Directive 93/85/EC.

It is permitted to import seed potatoes from Canada into the EU under derogation. During inspections in Portugal and Italy there was evidence that the requirements for these imports were not always fully met upon embarkation in Canada.

4.4.5 Poseidom and Poseima

These programmes are aimed at the French Overseas Departments, The Azores and Madeira. Activities in the phytosanitary field are subsidised. Regular Monitoring Committee meetings were held and inspections were carried out in the framework of the two programmes in the French Overseas Departments, Guyana and on the Azores.

4.4.6 Central and Eastern European Countries

A mandate to conduct equivalency negotiations, initially with thirteen third countries (Bulgaria, Czech Republic, Hungary, Poland, Romania, Slovak Republic, Argentina, Chile, Uruguay, Australia, Canada, New Zealand and USA), was given to the Commission by the Council on 25 February 1995. During 1997, negotiations continued in respect to Hungary and the Czech Republic. On the invitation of Romania, the Office visited its Plant Protection Service to elaborate a first profile of this service, with view to future accession.

4.4.7 Training

The Office organised a seminar for Member States' inspectors in Foligno (Italy) relating to inspection procedures for third country imports. An EU financial contribution was made for inspectors attending an EPPO seminar in York (United Kingdom). Member States' inspectors participated in the EC KAROLUS Programme, which includes the temporary placement of inspectors with different Member States.

4.4.8 Europhyt

Europhyt is a notification and mutual information network set up as a «real time» connection between Plant Protection Services for notification of interceptions, outbreaks and/or presence of harmful organisms. From the information loaded in Europhyt, up-to-date statistics are generated and can be used as an effective tool in the targeting of plant health inspections. In 1997, work concentrated on inputting data and testing Europhyt's reliability before giving access to the Member States in 1998.

4.4.9 Genetically Modified Organisms (GMOs)

Plans were developed for future inspection and control. These concern mainly the control organisations, their responsibility, training and performance regarding GMOs. The GMO authorisation processes and their placement on the market in connection to food safety will be monitored. Controls by the competent authorities relating to the importation of GMOs and related products will also be assessed.

4.4.10 Pesticides

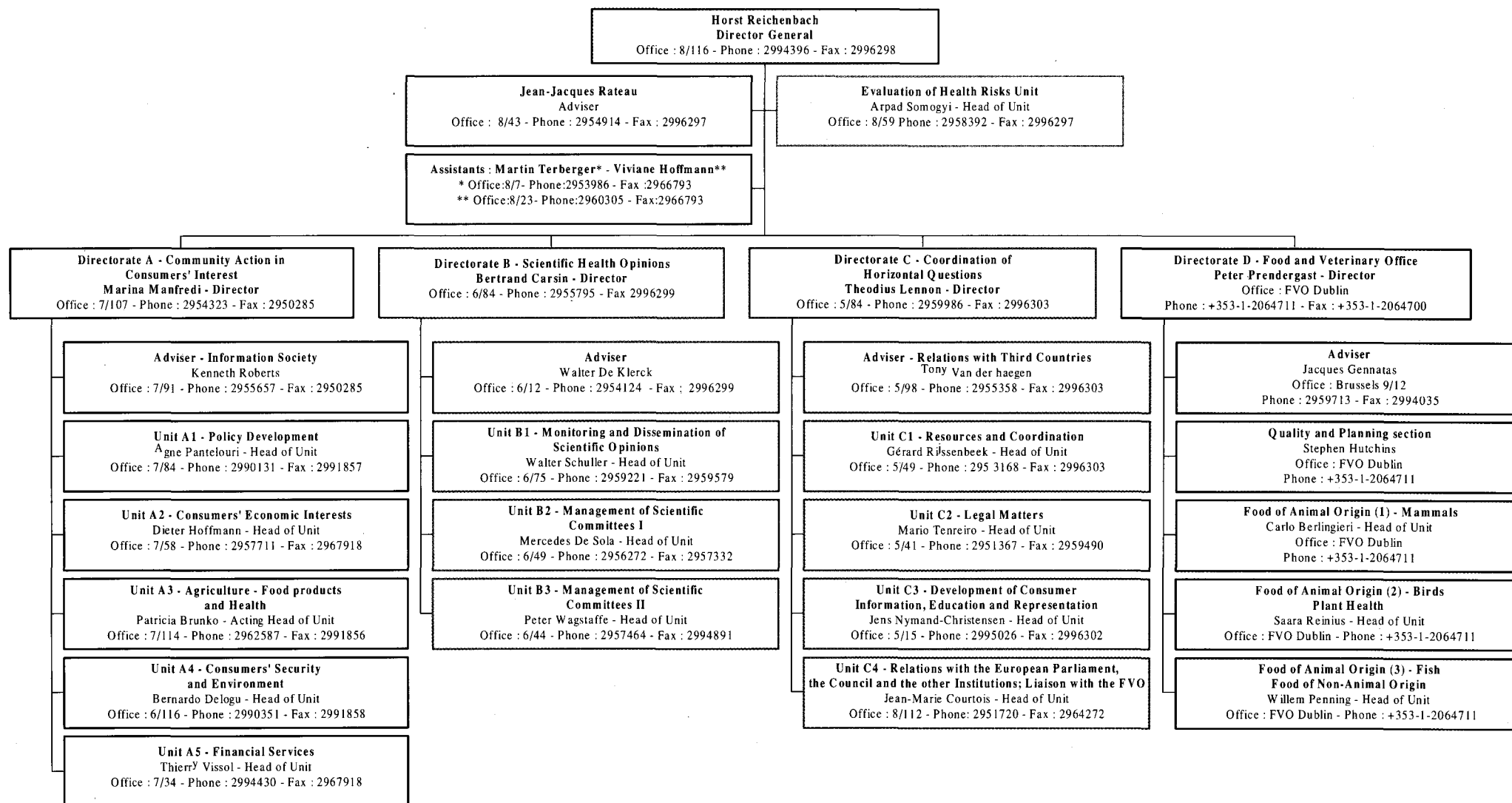
Plans were also developed for future inspection and control activities concerning pesticide use and residues in products of plant origin. Reports submitted by Member States, according to Article 4 of Council Directive 90/642/EEC and Article 17 of Council Directive 91/414/EEC on the monitoring of pesticide residues and control measures on their uses, underwent an initial assessment.

4.4.11 Organic Farming

Decisions concerning future inspection and control activities were also made with respect to organically produced foodstuffs. Initially the Office's activities will focus on those third countries that have entered into an equivalency agreement with the EU, in accordance with Article 11 of Council Regulation (EEC) No 2092/91.

Directorate General XXIV

Consumer Policy and Consumer Health Protection



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