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**REPORT FROM THE COMMISSION TO THE COUNCIL
AND THE EUROPEAN PARLIAMENT**

**Cooperation between administrations
for enforcement of internal market law
- a progress report -**

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I - Introduction

1. This report provides a survey of progress made to ensure that the enforcement of Community law on the internal market was more consistent by promoting cooperation and mutual assistance between administrations in the different Member States. This is an objective which responds to needs expressed by business, consumers, Member States' governments and EC institutions. It was announced in the Commission's Strategic Programme for the Internal Market¹.

The Commission set out a framework for enforcement cooperation in its Communication of 16 February 1994 on the development of administrative cooperation in the implementation and enforcement of Community legislation in the internal market². The Council consequently adopted a Resolution³ on 16 June 1994 on the same topic. The Economic and Social Committee also emphasized the same point⁴ and most recently the French Council Presidency made it a major focus, linking the question of enforcement especially with the levels of penalties for non-compliance with Community rules. Following the Commission's communication on the role of penalties in implementing Community internal market legislation⁵, the Council adopted a Resolution on 29 June 1995, setting out a common approach to this issue⁶. This Resolution stressed that "... administrative cooperation must be strengthened, where necessary, in those sectors where it is under-developed and must in any event satisfy the requirements of effective uniform implementation of Community rules".

2. The Council resolution of 16 June 1994 had called, among others, for three specific actions in this regard:

- i) the Member States were called upon to notify to the Commission by 31 December 1994 a list of contact points for enforcement purposes in each of eighteen priority areas of Internal Market legislation, together with essential information on their enforcement structures for these areas;
- ii) the Commission was called upon to pursue the programme of discussions with the Member States it was already conducting in sectoral committees and working groups to find out what kind of cooperation was required in each area of legislation considered a priority;
- iii) the Commission was called upon, on the basis of these discussions, to propose improvements to existing arrangements, including any extensions to support measures for administrative cooperation, such as seminars, training and exchange programmes for enforcement officials and the publication of interpretative guides. This was also to include, where necessary, adjustments to legislation.

The following chapters report on progress under each of these headings.

1 Commission communication to the Council of 22 December 1993 "Making the most of the Internal Market" : Strategic Programme, (COM(93) 632 final)

2 COM(94) 29 final of 16.2.1994

3 Council Resolution of 16 June 1994 on the development of administrative cooperation in the implementation and enforcement of Community legislation in the internal market, OJ C 179, 1.7.1994, p. 1

4 Economic and Social Committee Opinion on the annual report on the functioning of the internal market, OJ C 393, 31.12.1994, p.14, in recommendation 2 : "implementation and control must be supervised rigorously."

5 Communication from the Commission to the Council and the European Parliament on the role of penalties in implementing Community internal market legislation, COM(95) 162 final, 3.5.1995

6 Council Resolution of 29 June 1995 on the role of penalties in implementing Community internal market legislation, OJ C 188, 22.7.1995, p.1

II - Notification of contact points

3. All Member States have now notified contact points for most of the priority areas identified in the June 1994 Resolution. Some legislation already included requirements for enforcement contact points to be notified to the Commission, for example Directive 93/99 on the control of foodstuffs and Directive 89/48 on the recognition of diplomas. The Commission did not set out to replace or duplicate these pre-existing systems, but rather to confirm that they were functioning correctly. The purpose of such contact points is to place officials responsible for enforcing internal market legislation in touch with one another. Where control or surveillance is decentralized, communications may have to pass through a central coordinator at national level. However, it is noteworthy that notifications have been made for some regional authorities, such as individual German Länder.

4. The data concerning contact points generally includes the designation of the administrative unit directly involved in the Member State's administration (or the Commission) and a direct fax number. Most include a named person and give his or her direct telephone number. Some notifications also include the languages which the contact points can speak or read and their electronic mail (E-mail) addresses. In some cases an official in the Member State's Permanent Representation in Brussels is given as a contact point. All the contact points have been placed on a database, from which print-outs or information diskettes are distributed to those concerned.

Table 1 indicates, for each area of legislation, which Member States had notified contact points when this communication was finalized (27.11.95). Where there are sub-areas within an area of legislation, the table indicates whether full or partial notification was received of contact points for each sub-area. The latter case is indicated by a letter "P" in a shaded square. A black square shows that no notification has been received. The database also contains data on contact points for three areas which were notified to the Commission separately from this exercise, those of dual-use goods, drug precursors and recognition of diplomas (listed under freedom of establishment); notifications for all three areas are complete for all Member States.

The table shows that in this exercise only one Member State has failed to notify contact points in more than one or two areas. Greece has not yet notified contact points in four of the eighteen areas listed in the Council Resolution, and has only made partial notifications in others.

National contact points for broadcasting have not yet been notified in two Member States. The Commission especially requested a detailed breakdown of contact points in the transport area, and only seven of the Member States have made this full notification (Spain notified a single contact point for the whole transport field). In this table only two of the areas from the Annex to the Council Resolution of 16 June 1994 are shown with their breakdown into sub-areas, those of "foodstuffs, animal and plant health and veterinary medicines" and "taxation". The sub-area with the least notifications is direct taxation.

5. Many of the contact points notified appear to be officials principally concerned with legislation or policy rather than control of marketing of a product or service or the enforcement of legislation on the ground. The Commission considers that links between policy coordinators and their market control colleagues will need to be ensured for information on enforcement to pass quickly from one Member State to another. Similarly, some of the areas referred to in the Council Resolution of 16 June 1994 are very broad. A single contact point on technical harmonization directives, for instance, would need to cover several distinct areas of legislation, from medicines to toys. The extent to which the contact points notified are actually used will give an indication of how appropriate they are.

Table 1 - *Notifications of contact points for each area, by Member State as at 27.11.95*

MEMBER STATE:	B	DK	D	EL	E	F	IRL	I	L	NL	A	P	FIN	S	UK
1. Technical harmonization: directives to remove barriers to trade				P				P							
2. Public procurement															
3. Firearms															
4. Dual use goods															
5. General Product Safety Directive															
6. Telecommunications								P							
7. Foodstuffs, animal and plant health, veterinary medicines															
a) foodstuffs															
b) veterinary controls															
c) phytosanitary controls															
d) veterinary medicines															
8. Notification of technical regulations - Directive 83/189															
9. Customs and Excise															
10. Taxation									P			P			P
a) direct taxation															
b) indirect taxation															
11. Drug precursors															
12. Cultural goods															
13. Right of establishment															
14. Company law															
15. Insurance, banking, securities															P
16. Intellectual property															
17. Broadcasting															
18. Transport		P		P		P						P	P	P	

(P = partial notification for area; black square = not notified yet; all others notified)

It is important to mention that the Commission has undertaken to apply the principles of data protection laid down by Directive 95/46/EC⁷. Consequently access to the personal information provided will be strictly limited to those Commission services and those parts of Member States' administrations which are directly involved in the particular enforcement co-operation exercise in question. Contact persons will be provided with full information about this and about the purposes for which their details are used. They will be informed and their consent obtained in advance of their data being distributed to any other specific bodies.

Little information on enforcement structures and procedures has been received, although the Council Resolution called upon Member States to supply such information.

6. Looking to the future, other steps could also be taken by the Member States to ensure that the system of contact points now in place can be used more effectively, for instance by establishing contact points to give private individuals and business (especially small and medium-

⁷ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ L 281, 23.11.95 p. 31

sized enterprises - SMEs) an interface with the authorities of each Member State, in order to enable them to draw attention to barriers to free movement or trade. Examples are the UK Single Market Compliance Unit and the Danish Trade Barriers Committee. A recent Council Resolution⁸ called for the establishment of such contact points for enterprises, in particular SMEs, and another⁹ invited the Commission to send the Council a report of their findings. So far very few Member States have implemented this political commitment.

Member States will not be seen to be doing their best to eliminate barriers to trade and the free movement of persons as long as such contact points are not made available to address problems in the internal market with as little bureaucracy as possible.

III - Programme of discussions

7. Discussions on enforcement cooperation were held during 1994 and 1995 in all the eighteen areas of legislation listed in the Annex to the Council Resolution of 16 June 1994 (see the Annex to this Communication), except for broadcasting.

The objectives of the discussions have been fourfold:

- to identify the need for mutual assistance in each sector or area of activities (information requirements and the means of satisfying them);
- to determine how far these needs have already been satisfied;
- where necessary, to encourage participants in the discussions to introduce or extend enforcement cooperation;
- where this has not been done already, to compile lists of contact points in the Member States.

A detailed examination of enforcement cooperation in these sectors is given in the Annex.

8. These issues have been raised in meetings of **committees and working groups** organized by the Commission and involving representatives of the Member States' administrations with responsibilities in the area concerned. In parallel, the Advisory Committee for Coordination in the Internal Market Field (IMAC)¹⁰ has been kept informed of progress, particularly on the contact point issue.

The specialist committees or other bodies consulted fall into three categories:

- those whose sole purpose is to ensure enforcement cooperation, (e.g., the Standing Committee for Administrative Cooperation in the field of Indirect Taxation - SCAC)
- those with a regulatory or advisory role, but which spend part of their time on enforcement cooperation (e.g., the Standing Veterinary Committee) and

⁸ Council Resolution of 10 October 1994 on giving full scope to the dynamism and innovatory potential of small and medium-sized enterprises, including the craft sector and micro-enterprises, in a competitive economy, OJ C 294, 22.10.1994 - last dash of section III, p.7

⁹ Council Resolution of 21 November 1994 on the strengthening of the competitiveness of Community industry, OJ C 343, 6.12.1994 - paragraph III.4., p.4

¹⁰ Commission Decision 93/72/EEC of 23 December 1992 on the setting-up of an Advisory Committee for coordination in the Internal Market field, OJ L 26, 3.2.1993, p. 18

- those which deal with policy issues rather than enforcement, but which may provisionally act as a channel of information between national enforcement authorities, and between them and the Commission (e.g., the Advisory Committee for Public Procurement).

The Commission is concerned that the cooperation described in the Annex, which in a few areas is only indirectly connected with enforcement of the rules in the field, should become more centred in enforcement issues.

One means of communication which is already used in several areas was given special attention in the discussions, namely electronic data networks, and the lessons learnt from those which already exist should be applied to future projects.

IMAC has been kept informed and was consulted about this progress report.

9. A number of areas not mentioned in the Council Resolution of 16 June 1994 are covered in the Annex to this report, namely social policy, public administration and competition policy, as they underpin the operation of the Single Market. There are also final sections on Telematic Networks between Administrations and the Karolus exchange programme¹¹.

10. While needs vary according to the area of Community activity in question, some common points can be made on the discussions so far.

Firstly, the extent of enforcement cooperation in place varies considerably between the priority areas of Community legislation. These may be broadly divided into four categories:

1. those where cooperation between administrations is already strong:
these include **customs, VAT, veterinary and plant health controls, banking, insurance and securities** (and, in addition to the priority sectors, **social security for migrant workers**);
2. those where new arrangements for enforcement cooperation have recently been introduced and where surveillance of these systems is necessary:
these include **pharmaceutical products, foodstuffs and dual use goods**;
3. those where cooperation exists, but to a variable extent:
these include **firearms, cultural goods, product safety, legal metrology, transport and telecommunications**.
4. those where the Commission believes that cooperation between administrations for the enforcement of Community legislation still needs to be firmly established:
these include some of the "**New Approach**" directives (especially those which have very recently entered into force), **public procurement**, the "**Television without frontiers**" directive and the **Data Protection Directive**.

11. The needs for further cooperation are also very different from area to area. They range from exchange of specific numerical information (as in taxation, customs and statistical cooperation) to a need to understand procedures for placing products or services on the market in other Member States.

In technical areas, such as medicinal products or terminal equipment, information needs to be exchanged on testing techniques and the characteristics of the products or services in question.

¹¹ Council Decision 92/481/EEC of 22 September 1992 on the adoption of an action plan for the exchange between Member State administrations of national officials who are engaged in the implementation of Community legislation required to achieve the internal market, OJ L 286, 1.10.1992, p. 65

Other needs frequently expressed include the translation of information, guidance in interpreting the legislation, the drawing up of procedural rules for information exchanges, and, above all, **coordinated training of enforcement authorities.**

Another need which has become apparent in some areas, such as customs, drug precursors and arms, is clarification of the relationship between measures taken under the EC Treaty and those to which inter-governmental cooperation under Title VI TEU applies.

12. Officials in the Member States and the Commission were eager to have the contact points in their sectors at their disposal. Those who dealt with enquiries from firms sometimes needed contacts in other sectors, to reduce the time taken to resolve problems. The Trade department of one Member State had to contact the authorities of another country through its embassy, for instance, to enable beer to be marketed in that Member State without having to be tested again; direct contact with the foodstuffs enforcement authorities would have solved this problem more quickly.

13. Members of the committees and groups consulted generally looked to the Commission to provide coordination, and in many cases funding for cooperation, as in the establishment of electronic data networks. Exceptions to this were banking supervisory authorities, which cooperate under a series of bilateral memoranda of understanding, direct taxation authorities, which cooperate under Directive 77/799/EEC and the bilateral tax conventions and to some extent telecommunications control authorities.

14. Sectors where cooperation was either developing or already well developed were generally aware of the need for joint training of enforcement officials. Those who had experience of the KAROLUS exchange programme had generally found it very useful, but the benefits had not been spread widely enough. It was often felt that those who would benefit most from the exchange of experience had no time to go on extended exchanges. And there was also limited capacity for administrations to act as host. These factors may have resulted in the target numbers of exchanges not being reached. Drawing from the experience of other programmes, such as MATTHAEUS for customs officials, a desire was expressed in a number of sectors for shorter exchanges or visits and for joint seminars and similar training activities, in addition to conventional exchanges.

IV - Improvements to existing arrangements

15. Conclusions at this early stage must be tentative. However, further action is needed to ensure that the objective of even enforcement of Community law across the Union is achieved. The Commission would particularly recommend the following steps:

Contact points

- Member States should complete notification of contact points for the eighteen areas listed in the Annex to the Resolution of 16 June 1994 as soon as possible.
- They should also provide sufficient information on their enforcement structures and procedures.
- Member States should ensure that the lists of contact points are kept up to date and notify the Commission of any changes.

- The Commission will investigate the use of on-line versions of these lists.
- The Commission will, during 1996, extend its monitoring of the work of the contact points notified in this exercise to find out how many times they communicate, how useful the results of this cooperation are and how cooperation could be improved, and will report to the IMAC.
- The Member States should as soon as possible implement the Council Resolution of 10 October 1994 by establishing contact points for the public, especially for small and medium-sized enterprises, in order that the system of inter-administration contact points now in place can yield its full benefits.

More facilities for joint training

- The Commission will examine the possibility of modifying the Karolus exchange programme, in particular to include specific training sessions on similar lines to the present MATTHAEUS and MATTHAEUS-Tax seminars. The accent would be on joint training between different States' officials and greater flexibility in exchanges.
- The Commission and the Member States should also encourage more short-term mutual joint visits or joint inspections such as those currently carried out in the GLP and foodstuffs areas, in addition to exchanges and training sessions, as these are needed to provide the cross-Community perspective which helps officials to enforce the rules evenly.

Basis for cooperation

- Finally, where appropriate and in consultation with the Member States, the Commission will, by the end of 1996, endeavour to draw up ground rules for enforcement cooperation in each sector or area of legislation, dealing, for instance, with the precise type of information to be exchanged and at what stage in the enforcement process. Only such "tailor-made" solutions, respecting the specificities of each sector, can create the confidence required between administrations. Rules of the game, to be followed by all parties involved, have been found to be particularly necessary for the "New Approach" directives. If in specific sectors it proves impossible to achieve satisfactory enforcement of the rules in any other way, for example under Article 5 of the Treaty, the Commission will consider proposing legislation imposing such rules for cooperation.

The Commission calls upon the Council and Parliament to take note of the above recommendations.

Annex
Enforcement cooperation in specific areas
of Internal Market legislation

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The description of enforcement cooperation in each of the areas of legislation concerned is divided into a maximum of five sections:

- 1° -Introduction;
- 2°- Existing mechanisms for enforcement cooperation;
- 3° -Needs for cooperation;
- 4° -Impediments to cooperation;
- 5° -Next steps.

Part I

Priority areas identified in the Council Resolution of 16 June 1994

1. Technical harmonization: directives on the elimination of barriers to trade

This sector has been broken down into the following sub-areas:

- A - New Approach: Toys, Machines, Personal protective equipment, Electromagnetic compatibility, Gas appliances, Pressure equipment, Medical devices, Metrology and Explosives
- B - Pharmaceutical products
- C - Good Laboratory Practice (GLP)

Conformity testing and market supervision in relation to these directives is one of the areas for which the Karolus programme of exchanges between enforcement officials is available. For more details see section 23 on the Karolus programme.

1 A — New Approach: Toys, Machines, Personal protective equipment (PPE), Electromagnetic compatibility (EMC), Gas appliances, Pressure equipment, Medical devices, Metrology and Explosives

1° Introduction

The application of these directives is only now becoming mandatory. They have also been amended by Directive 93/68/EEC¹², which imposes CE marking for the different products covered and entered into force on 1 January 1995. A transitional period lasts until 1 January 1997, after which such marking will be compulsory in each sector (as it is currently for toys). Thus cooperation on enforcement is only now starting to develop.

2° Existing mechanisms for enforcement cooperation

- Toys Directive¹³: application since 1.1.90.

Contacts between the Commission and the Member States occur mainly when safeguard measures are reported by national supervisory authorities, before notifications are passed on to the other Member States. These consultations are case by case and generally bilateral. In order to acquire further information on implementation of Directive 88/378/EEC in each country and to permit an exchange of views on a number of problems in interpreting and implementing it, the Commission organized in 1995 a number of bilateral meetings with national supervisory authorities and a meeting between the Member States' supervisory authorities. The discussions showed that exchanges of information were necessary as a matter of urgency both for supervisory authorities and for the bodies notified.

¹² OJ L 220, 31.8.1993, p. 1

¹³ Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys, OJ L 187, 16.07.1988, p. 1

- Machines Directive¹⁴: application since 1.1.93, mandatory since 1.1.95, (safety components and machinery for lifting or moving persons¹⁵: 1.1.97):
Discussions are taking place on the type of information to be exchanged and means for exchanging it (work is in progress on developing forms adapted to the essential requirements of the Directive);
The Committee established under the Directive is working on common interpretations and has reached agreement on particular issues, such as what parts of technical files are to be submitted and when, and clarification of the types of machinery excluded from the Directive.
- The PPE Directive¹⁶ (application 1.7.92, mandatory since 1.7.95)
Work so far has mainly focused on interpretation problems and certification issues.
- Electromagnetic compatibility (EMC) Directive¹⁷ (application 1.1.92, mandatory 1.1.96) and the Low Voltage Directive¹⁸ (LVD, application 21.8.74, DK 21.12.79).
The LVD is a fully "New Approach" Directive by virtue of the Council Decisions concerning the modules for the various phases of the conformity assessment procedures¹⁹ and of Directive 93/68/EEC on CE marking.¹² EMC is the only case where Member States are required to notify competent authorities for the implementation of a New Approach Directive to the Commission.
Discussions have been held twice for the LVD and 3 times for the EMC Directive on needs and information to be exchanged. Meetings of national enforcement officials have examined the enforcement systems of different Member States and have set out to define the form which cooperation should take. These have addressed the definition of
 - (a) lists of contact points, responsible both for application of the Directives and for market surveillance;
 - (b) the content and type of information to be exchanged between these authorities; and
 - (c) the means to be used for developing these contacts: fax, IDA networks, etc.
- Gas appliances²⁰ and Pressure vessels²¹: application 1.1.92 and 1.1.90, mandatory from 1.1.96 and 1.7.92 respectively. Work is going on concerning interpretation issues. Guides for industry and regulators are under preparation - a guide has been published for the gas sector, in particular listing pre-market contact points
- Medical Devices: application: Active Implantable²² 1.1.93; Medical Devices²³: 1.1.95; mandatory from 1.1.95 and 14.6.98 (in certain cases 1.7.2004) respectively. On 28 March 1995,

14 Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery, OJ L 183, 29.6.1989, p. 9

15 Council Directives 91/368/EEC of 20 June 1991 and 93/44/EEC of 14 June 1993 amending Directive 89/392/EEC on the approximation of the laws of the Member States relating to machinery, OJ L 198, 22.7.1991, p. 16 and L 175, 19.7.1993, p. 12

16 Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the design of personal protective equipment, OJ L 399, 30.12.1989, p. 18

17 Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, OJ L 139, 23.5.1989, p. 19

18 Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits, OJ L 77, 26.3.1973, p.29

19 Council Decision 90/683/EEC of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives, OJ L 380, 31.12.1990, p. 13, as amended by Decision 93/465/EEC of 22 July 1993, OJ L 220, 30.8.1993, p. 23

20 Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to appliances burning gaseous fuels, OJ L 196, 26.7.90, p. 15

21 Council Directive 87/404/EEC of 25 June 1987 on the harmonization of the laws of the Member States relating to simple pressure vessels, OJ L 220, 8.8.1987, p. 48, as amended by Directive 90/488/EEC, OJ L 270, 2.10.1990, p. 25

22 Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical equipment, OJ L 189, 20.7.1990, p. 17

during the Competent Authorities/Member States experts' meeting, a draft document and form for information exchange under the rapid alert system was presented to Member States by the Commission for comments.

- Legal Metrology: Directive 90/384/EEC²⁴ applies 1.1.93 and has been mandatory since 1.1.95. A feasibility study is in progress on a database to allow exchange of information between notified bodies and with market surveillance authorities.
- Explosives²⁵ (application 1.1.95, obligatory from 1.1.2003): cooperation is required for enforcement of the part of the Directive relating to the transfer of explosives. In this case, the agreement of various competent authorities is required. Cooperation takes place via the committee and also on a case by case basis.

In these "New Approach" areas there has only been a limited experience so far. However, a number of exchanges between officials in these areas have occurred under the KAROLUS programme and more are planned for 1996.

Apart from one seminar at Union level that has been organized for PPE and one for Machines, knowledge is mainly based on seminars organized by individual Member States, contacts through attendance at committee meetings and bilateral exchanges during visits and/or missions.

3° Needs

A need for common interpretations of the terms used in these Directives is being met through "guides".

The guides to the Machinery and EMC Directives were published in 1993, that for gas appliances in February 1995. Information packs containing guidelines on pressure vessels and medical devices are also issued on request.

A guide to the implementation of the Toys Directive will be drawn up by the Commission in consultation with national authorities. This guide will shed light on the limits on the definition of a toy as given in the Directive, the kinds of compliance tests to be applied to certain toys and the interpretation of compliance tests.

These activities also take account of the results of the ongoing coordination with and between the notified bodies in each area. It should be noted, however, that **interpreting** legislation is strictly speaking a matter for the Court of Justice.

The needs for improvement are not substantially new - reference should be made to the conclusions on administrative cooperation in "The Single Market in 1994"²⁶.

4° Impediments

No systematic inventory has been made of material difficulties, lack of resources or communications infrastructure. Experts in the Commission working groups are not necessarily contact points and are even not working in the relevant Ministries that would be in charge of enforcement at national level. Efforts so far have concentrated on enhancing bilateral and multilateral contacts

²³ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12.7.1993, p 1

²⁴ Council Directive 90/384/EEC of 20 June 1990 on the harmonization of the laws of the Member States relating to non-automatic weighing instruments, OJ L 189, 20.7.1990, p 1

²⁵ Council Directive 93/15/EEC of 5 April 1993 on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses OJ L 121, 15.5.1993 p. 20

²⁶ COM (95)238 final, 15 June 1995, para. 123

at a personal level, which will at a later stage enable the administrations involved to assess the right technical means to put in place.

The fact that there appear to be doubts in some quarters about the effective implementation of Community rules by all Member States and about the existence of a common will to improve cooperation indicates that the "rules of the game" still have to be defined and must be applied by all Member States.

1 B — Pharmaceutical Products

1° Introduction

Over the last thirty years, EC pharmaceutical legislation has progressively covered all industrially produced medicinal products for human and animal use. Specific rules apply to particular types of medicines, such as vaccines, blood products and radiopharmaceuticals, with harmonized quality, safety and efficacy requirements.

In June 1993, the Council adopted three Directives²⁷ and a Regulation²⁸ which together form the legal basis of the new European system for the authorization of medicinal products. This system became operational in 1995 when the European Agency for the Evaluation of Medicinal Products (EMA) opened its doors in London.

Two marketing authorization procedures are now available:

- a centralized procedure leading to a single marketing authorization valid throughout the EU. This procedure is compulsory for medicinal products derived from biotechnology and available at the request of companies for other innovative new products;
- and a decentralized procedure based upon the principle of mutual recognition of national authorizations. The purpose of the decentralized procedure is to permit the extension of a marketing authorization granted by one Member State to one or more of the other Member States by means of recognition of the original authorization. Should the national authorization not be recognized by other Member States, and after exhaustion of all possibilities for the resolution of the issues directly by the Member States concerned, the dispute will be submitted to binding Community arbitration;

2° Existing mechanisms for enforcement cooperation

A number of committees and working parties have been set up since 1975 to deal with various questions relating to pharmaceutical harmonization, administrative collaboration, alert systems and advice to the Commission.

- **The Pharmaceutical Committee** was set up by Council Decision 75/320/EEC to examine any question relating to the preparation and application of pharmaceutical legislation. It consists of senior representatives from the Member States' administrations who are experts

²⁷ Council Directives 93/39/EEC of 14 June 1993 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products, 93/40/EEC of 14 June 1993 amending Directives 81/851/EEC and 81/852/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and 93/41/EEC of 14 June 1993 repealing Directive 87/22/EEC on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology, OJ L 214, 24.8.1993, pp. 22, 31 and 40

²⁸ Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, OJ L 214, 24.8.1993, p. 1

in public health matters. Questions of interpretation and enforcement of EC pharmaceutical legislation are examined jointly within this Committee.

- Two scientific Committees, the Committee for Proprietary Medicinal Products (**CPMP**) and the Committee for Veterinary Medicinal Products (**CVMP**) set up by Council Directives 75/319/EEC and 81/851/EEC, have been created to facilitate the adoption of common positions on marketing authorizations of medicinal products. These two committees and their various working parties have been used as a corner-stone for the creation of the European Agency for the Evaluation of Medicinal Products (**EMEA**). Each Committee has two members from each Member State and both are assisted by a European list of 1600 experts.

The EMEA was conceived as an interface of coordination and cooperation of national scientific resources, whether human, intellectual or material. Its role is that of a catalyst for the deployment of resources, in particular through the establishment of networks of European resources of national origin. The national competent authorities remain the pillar of the new European registration system. They will continue to perform their duties, for example inspecting manufacturers of medicinal products and performing **pharmacovigilance** activities on behalf of the EU.

A **telematic network** is currently being set up between the European Commission, the EMEA and the national authorities. Its purpose is to ensure fast and secure transmission of data such as assessment reports and pharmacovigilance alerts.

Regarding **industrial manufacture** of medicinal products, a system of national authorizations and supervision has been developed since 1975 based on the principle of genuine mutual recognition with appropriate procedures for administrative collaboration on inspection matters, including an alert system on quality defects.

With regard to **pharmaceutical inspections**, harmonization of Good Manufacturing Practice continues in the Working Party on Inspection and Control of Medicinal Products set up by the Commission.

Pharmaceutical supervision officials have taken part in the **KAROLUS** programme of **exchanges of officials** between national administrations (see section 23 below).

3° Needs

Making a success of the new European system for medicines is a challenge which can only be achieved if Member States are fully committed and provide the system with experts of the highest scientific quality.

Knowledge of other national systems also needs to penetrate beyond the level of officials who attend the committees and working parties. No Community programme except **KAROLUS** covers training of the officials closest to the terrain and national resources are scarce.

Detailed information on technical criteria and administrative procedures for national approval are needed by those responsible for approvals (who are also, generally speaking, responsible for market control). There needs to be mutual confidence in the efficacy with which these procedures are applied in practice.

4° Next steps

The Working Party on Inspection and Control of Medicinal Products has suggested that these two-month exchanges under the Karolus programme should be supplemented by workshops, seminars and the like to increase mutual knowledge on the processing of applications and market

supervision, analogous to those available under the MATTHAEUS programme. This Working Party has repeatedly suggested that the KAROLUS programme could be used to build up mutual confidence through joint inspections and training sessions, and that the duration of the "exchanges" should be adapted to what it saw as the actual needs in this area (i.e. 1-2 weeks rather than two months).

1 C — Good Laboratory Practice (GLP)

1° Introduction

Laboratory tests are required prior to the putting on the market of industrial chemicals, pesticides, foodstuffs, animal feedingstuffs, cosmetics and pharmaceutical products, and EC legislation covers GLP in these areas²⁹.

The aim is mutual recognition of test results, avoidance of repeat testing, thus facilitating the free circulation of these products at lower marketing costs.

Compliance with the internationally agreed GLP standard should guarantee that test data are accepted by the authorities of all Member States.

2° Existing mechanisms for enforcement cooperation

Informal meetings take place with the national monitoring authorities, workshops have been organized to familiarize participants with other Member States' systems, databases concerning inspections, administrative infrastructures and national legislation are annually updated by the Commission and distributed in hard copy form. Information exchanges also take place within an OECD framework.

The latest development is the establishment of a system of Mutual Joint Visits (MJVs). This programme is a voluntary scheme consisting of a series of informal visits of one week at most by a team of 3 observers. These are inspectors from national GLP monitoring authorities of other Member States. The Commission coordinates but does not physically participate in the visits.

The goal is not to criticize Member States when lack of conformity with the GLP standards is found, but to help them to adopt the same approach as other Member States. The result is openness and transparency, leading to mutual understanding and more confidence.

3° Needs

A certain lack of mutual confidence in each others compliance monitoring systems needs to be overcome. The Member States' GLP inspectorates are fully aware that information exchange is the keystone for mutual confidence.

Two main fields of information exchange can be identified:

- (a) that concerning application and interpretation of the texts, which takes place at meetings, workshops, databases and within the OECD, and mainly aims at overcoming problems due to real or presumed differences in application and interpretation of legal texts, and

²⁹ e.g. Council Directive 87/18/EEC of 22 December 1986 relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances; OJ L 15, 17.1.1987, p.29; Council Directive 88/320/EEC of 9.6.1988 on the inspection and verification of good laboratory practice, OJ L 145, 11.6.1988, p.35; Council Decision 89/569/EEC of 28 July 1989 on the acceptance by the EEC of an OECD decision/recommendation on compliance with principles of good laboratory practice, OJ L 315, 28.10.1989, p. 1.

- (b) that related to compliance surveillance. The MJV programme enables delegations to compare the real functioning of national mechanisms. This is a far-reaching form of information exchange as well as a mechanism for circumventing formalistic approaches.

4° Impediments

No major obstacles are expected, so long as the system functions on a voluntary and rather informal basis.

2. Public procurement

1° Existing mechanisms for enforcement cooperation

Administration cooperation with the Member States currently has two aspects:

- meetings of an advisory committee bringing together representatives of the administrations in charge of public procurement, to study proposals for amendments to the existing directives, to look into questions of their interpretation and any difficulties in their implementation, or any other matter concerning enforcement of Community law on public procurement. There is also an Advisory Committee on the Opening-up of Public Procurement, composed of independent experts whose business and industrial experience and whose competence regarding public procurement at Community level are widely recognized, whose task is to contribute to discussion on the various problems concerning public procurement;
- package meetings with each Member State to examine, with the various national administrations or authorities concerned, cases in dispute which come to the Commission's attention, either through complaints or after investigations of its own.

A significant number of exchange visits between officials from the Member states to study aspects of public procurement policy and practice are being arranged under the Karolus Programme. Sixty-six such exchanges had been approved by the mid-November 1995, and forty-two of these had been completed.

2° Needs

The directives³⁰ require specific information for tender notices, contract award notices, periodic information notices and notices on the existence of a qualification system to be printed and published in the Official Journal. Provision of on-line access to public procurement opportunities through Tenders Electronic Daily (TED) has been available since 1986. More than 500 notices are currently being published each day.

Under the directives Member states are required to provide regular statistical reports on contracts awarded by contracting entities. The Commission is encouraging the development of technologies and services required for information management and electronic tendering.

Under the Remedies Directives³¹ the Commission needs to know how complaints are dealt with at a national level, as do the other Member States, in order for them to have confidence in the equal treatment of their firms, but for the moment all the Member States are reluctant to provide such information.

The two Consultative Committees on Public Procurement both consider questions of interpretation. The adoption of interpretative texts approved by these committees could help in arriving at common interpretations of the texts.

³⁰ such as Directives 93/36, 93/37 and 92/50 coordinating procedures for the award of public supply, works and service contracts respectively, OJ L 199, 9.8.1993, pp. 1 and 54; OJ L 209, 24.7.1992, p. 1

³¹ Directive 89/665/EEC of 29 December 1989 on the coordination of the laws, regulations and administrative provisions relating to the application of review procedures to the award of public supply contracts, OJ L 395, 30.12.1989, p. 33; Directive 92/13/EEC of 25 February 1992 coordinating the laws, regulations and administrative provisions relating to the application of Community rules on the procurement procedures of entities operating in the water, energy, transport and telecommunications sectors, OJ L 76, 23.3.1992, p. 14

3° Next steps

The Commission is reflecting on the possibility of developing proposals for a common training programme (to be conducted by the Commission, Member States and business) to disseminate knowledge of the public procurement regime to all those involved in public procurement activities. It would hope for early action by the Council on such proposals.

The development of information technology may bring appreciable benefits in public procurement. Transparency in public purchasing is a key factor in ensuring that public purchasing procedures are able to provide the best cost/benefit ratio. The Commission has begun the pilot phase of a project called SIMAP (Système d'Information sur les Marchés Publics), the aim of which is to compile electronically all information concerning procurement by contracting entities in the Community and to disseminate them, electronically to all potential suppliers. If the project is to be effective, the collaboration of all those concerned is necessary, including of course the Member States.

In addition, in order to ensure that public procurement rules are complied with in the case of projects financed by Community funds, there has since 1988 been a sharing of tasks between the Commission and the Member States, based on the principle of subsidiarity: the Member States have to check whether such projects are carried out in compliance with public procurement rules. Unfortunately, most Member States have not allocated the necessary resources for this. In order to develop this approach, the Commission might propose that the Member States set up independent national authorities to ensure that public procurement rules are complied with in the case of projects financed by Community funds. Details of their operation would be left to the discretion of the Member States, provided that there was a guarantee of their being independent of the contracting entities and given the necessary resources. If such authorities are set up, they will of course have to be cooperation among them and between them and the Commission.

A further possible action would be for the central governments in the Member States and the (largely local or regional) contracting entities to use such independent structures for coordinating enforcement of the rules on all public procurement to which Community law applies.

The Commission recommends that this question be examined with the Member States.

3. Firearms

1° Introduction

Council Directive 91/477/EEC of 18 June 1991 on control of the acquisition and possession of weapons³² is the main accompanying measure for discontinuing checks on goods at internal frontiers in the case of weapons. It harmonizes aspects of legislation on firearms and lays down the formalities for movement in the Community.

2° Existing mechanisms for enforcement cooperation

The Directive provides for the Member States to inform each other on transfers of firearms and the acquisition and possession of firearms by non-residents.

It provides for the Member States to set up, by 1 January 1993, networks for exchange of information in order to comply with these obligations. They are to inform other Member States and the Commission of the national authorities responsible for sending and receiving this information.

The information exchange networks have been set up and are operating well.

3° Needs

Some Member States feel the absence of a structure (for example, a committee) which would enable representatives of national authorities to hold multilateral meetings from time to time and discuss practical problems posed by the implementation of the Directive.

4° Impediments

In November 1995, the Directive had still not been transposed by Austria, Finland or Sweden.

³² OJ L 256, 13.9.1991, p. 51

4. Dual Use Goods

1° Introduction

The system of export controls on dual-use goods consists of two pillars: Council Decision N° 94/942/CFSP on the joint action adopted by the Council on the basis of article J.3 of the Treaty on European Union and Council Regulation (EC) N° 3381/94 of 19 December 1994 setting up a Community regime for the control of exports of dual-use goods³³. The system applies from 1 July 1995.

The Regulation stipulates the need for administrative cooperation. A list of contacts has been established and national licence forms are drafted on the basis of a model form.

2° Existing mechanisms for enforcement cooperation

The Coordination Group on Export Controls of dual-use goods meets regularly to discuss administrative cooperation in this area. This Group has assisted the Commission in drawing up detailed procedures for administrative cooperation between Member States.

Five exchanges between export control enforcement officials have been approved under the KAROLUS programme. A seminar was organized in 1994 as part of the MATTHAEUS programme, for customs cooperation in the dual-use area.

3° Needs

Various provisions of the Regulation require close cooperation between the authorities of Member States, both those responsible for licensing and those responsible for customs (which in Community terminology includes post-exit controls), in particular:

- a) Licences issued by an authority in one Member State must be recognizable by the authorities in another Member State which has to enforce them.
- b) The licensing authorities of the Member State in which the exporter is established must consult the licensing authorities of the Member State in which the good is or will be located. No format has been foreseen.
- c) The effectiveness of post-exit control measures can be increased by cooperation between administrations.
- d) Member States may ask for an export licence for exports from their territory for dual-use goods not listed in Annex 1 of the Council Decision on the Joint Action. Transparency of these measures is in the interest of all Member States, and exchange of information on the authorizations foreseen in the Regulation could prove useful.

The Commission services will provide explanatory notes on provisions of the Regulation that could give rise to divergent interpretations.

All Member States already had a well functioning export control system before the entry into force of the Community system. However differing experiences of different administrations with certain categories of goods need to be remedied by a sharing of information.

An electronic data exchange infrastructure could facilitate the efficient and effective implementation of the Community system of export controls, but Member States want to assess at a later stage whether such an infrastructure is needed.

³³ OJ L 367, 31.12.1994, p. 1

5. General Product Safety

1° Introduction

Cooperation on enforcement of the rules in the sector of product safety is based on the various mechanisms provided by Directive 92/59/EEC on General Product Safety.

2° Existing mechanisms for enforcement cooperation

Directive 92/59/EEC This Directive established an "Emergency Committee", consisting of representatives from the Member States and the Commission services. In this Committee matters related to enforcement cooperation are discussed.

The Commission regularly submits working documents to the members of the Committee with a view to obtaining convergent practice in the application of the various mechanisms provided for in the Directive.

3° Needs

In July 1994 a questionnaire was submitted to the members of the Emergency Committee established under the General Product Safety Directive, with a view to identifying needs in terms of enforcement cooperation in this sector. Only a minority of Member States have provided the Commission with detailed answers to date.

4° Impediments

A few Member States have expressed their concerns as to their lack of resources and of communications infrastructure. Lack of training for inspectors was specifically mentioned in the context of obtaining as homogeneous an approach as possible in the framework of the Internal Market.

5° Next steps

A feasibility study on the computerization of the rapid information exchange system provided for in the General Product Safety Directive has recently been completed in the framework of the IDA Programme. Depending on the credits available, a pilot project with some Member States could start in the second quarter in 1996 and, if the results are positive, the project could be extended to all Member States.

Consideration should be given to Community support for country-specific training programmes for product safety enforcement officers.

6. Telecommunications

1° Existing mechanisms for enforcement cooperation

Commission Directive 90/388/EEC provides that all Member States should have a national regulatory authority for telecommunications, separate from the Telecoms Operators. So far as cooperation on enforcement of EU legislation is concerned, two committees are the most important fora for exchange of information, the Committee for Approvals of Terminal Equipment (ACTE)³⁴ and the Open Network Provision (ONP) Committee in the area of networks and services³⁵. (These are committees of Member States chaired by the Commission, which can act in both an advisory and a regulatory capacity.)

Cooperation on Telecoms issues also takes place through the International Telecommunications Union of the United Nations, and at the European level through the European Conference on Posts and Telecommunications (CEPT).

The ACTE is the chief forum for enforcement cooperation between Member States regarding terminal equipment.

There is intense activity in the area of seminars, conferences and consultancy studies at national and European levels - run both by the Commission and commercial companies - in which officials are involved. Cooperation also takes place through the Association of Designated Laboratories of the Notified Bodies, dealing with practical questions concerning the performance of procedures for certifying compliance of terminal equipment.

2° Needs

Liberalization of the telecommunications sector means that many of the tasks previously handled by administrations are nodded on a commercial basis by the telecommunications operators.

Coordination between administrations in Member States is still needed on licensing of telecommunications services, frequency allocation and numbering.

The electronic mail system between representatives of the Member States and between them and the Commission should be completed. This would be useful for the exchange of routine Committee documents and for keeping track of enforcement of the legislation.

The need is strongly felt for guidelines to be drawn up on the application of ONP principles. This is important in view of progress in discussions on the future of ONP, and especially with respect to future directives in this area (for example those on voice telephony and interconnection).

3° Impediments

Some national regulatory authorities for telecommunications, particularly in the smaller Member States, suffer from lack of resources. The specialist nature of telecommunications means that it is sometimes difficult for them to find staff with the necessary knowledge and experience.

4° Next steps

³⁴ Council Directive 91/263/EEC of 29 April 1991 on the approximation of the laws of the Member States concerning telecommunications terminal equipment, including the mutual recognition of their conformity, OJ L 128, 23.5.91, p. 1

³⁵ Council Directive 90/387/EEC of 28 June 1990 on the establishment of the internal market for telecommunications services through the implementation of open network provision, OJ L 192, 24.7.90, p. 1

Day-to-day exchange of information would be helped if all administrations had easy access to E-mail systems for document distribution.

7. Foodstuffs, animal and plant health, veterinary medicines

These are four distinct areas, which are therefore treated separately:

7 A — Foodstuffs

1° Introduction

In the foodstuffs sector, a form of administrative cooperation was embarked upon in 1984 with the setting-up of a network of contract points for reporting cases of serious danger concerning foodstuffs and exchanging the necessary information for dealing with the serious dangers to health which the system was able to identify. These arrangements were institutionalized in the Directive on general product safety³⁶.

2° Existing mechanisms for enforcement cooperation

Directive 89/397/EEC on the official control of foodstuffs set up further instruments of administrative cooperation:

- since 1993 figures concerning the results of national programmes of official controls on foodstuffs have been sent to the Commission annually;
- the Commission makes an annual recommendation concerning a coordinated Community programme of official inspections of foodstuffs.

Under Directive 93/99/EEC, a formal system of administrative cooperation has been set up. It came into effect on 1 May 1995. National inspection services give each other assistance in their task of supervising whether foodstuffs are in compliance with the rules governing them. Each Member State designates a single liaison body which transmits requests for assistance to other bodies and ensures that requests for assistance from other Member States are replied to.

The equivalence and effectiveness of national food control systems are evaluated by specific officials designated by the Commission.

Directive 93/5/EEC lays down procedures for scientific cooperation between the Commission and the Member States to be followed from June 1993 onwards.

Among the specific actions carried out using these various tools for cooperation are:

- the work on increasing transparency carried out by the Commission/Member States Working Party on the Official Control of Foodstuffs through summarizing the results of the annual inspection programmes of the Member States.
- the execution of the first coordinated Community programme of inspections in 1995, which demonstrated the advantages of certain inspection measures being carried out for the single market as a whole
- the beginning of missions to assess the effectiveness and equivalence of the Member States' national systems, which are carried out in cooperation between the Member States and the Commission. The first missions (United Kingdom, Italy and the Netherlands) took place in 1995. Clearly the effects of these assessment missions will assume their full proportions over the long term, in particular when all the Member States have been visited. However it already appears that these steps to create contacts with the practical realities of foodstuffs control have had very beneficial effects;

³⁶ Council Directive 92/59/EEC of 29 June 1992 on general product safety, OJ L 228, 11.8.1992, p. 24.

- the execution of the programme of scientific collaboration between the Commission and the Member States at their research institutes, which in 1995 covered topics such as aromas, microbiological criteria, the assessment of food consumption and various contaminants.

Finally, the Standing Foodstuffs Committee plays an important role in achieving consensus on how the legislation is to be implemented as do exchanges of officials under the Karolus programme.

3° Needs

Needs for the exchange of information between Member States and the Commission and for scientific cooperation are broadly covered by existing food legislation.

As regards official inspection, discussion in the Commission/Member States working group have shown up the need for a vade mecum or guidelines on how the national results of official inspection are to be communicated to the Commission. This should be adopted by the end of 1995 and should make national figures on official inspection of foodstuffs more transparent and more comparable.

4° Impediments to cooperation

Two problems arise here:

- ensuring that the results of the national and Community annual inspection programmes reported are as comparable as possible;
- ensuring rapid statistical processing at Community level so as to provide a synthesis of figures received.

In a system like scientific cooperation, where the scientific and technical resources are concentrated in the Member States, experience shows a balance is necessary between devolving responsibilities to the Member States and coordination at Community level, based on a precise definition of the tasks involved.

5° Next steps

High-performance tools for information exchange should be put in place, including for the transmission and processing of the large number of statistics involved. A study has been planned for 1996 to decide on the most suitable system.

Concrete experience in current administrative cooperation also shows that it would in certain cases be useful to have Community facilities for training inspection officials. The Karolus programme should be continued but might in some cases be redirected to include not only exchanges of officials but also training seminars or exchanges of experience.

As regards scientific cooperation, Community incentives should be retained, especially as regards defraying the administrative costs generated by cooperation work, the scientific work involved being financed by the Member States.

7 B — Veterinary Controls

1° Introduction

The veterinary sector has well developed arrangements for enforcement cooperation, reflecting the lengthy experience of legislation at Community level. In 1989 the Council adopted Council

Directive 89/608/EEC³⁷, setting out provisions on assistance between authorities and the communication of such information. This Directive places a strong emphasis on the role of the Standing Committees (see II).

2° Existing mechanisms for enforcement cooperation

The main area through which enforcement cooperation takes place is the regular meetings of the Standing Veterinary Committee (established in 1968) and the Standing Committee on Zootechnics (Regulatory Committees). During 1994 there were 31 meetings, with a total of 69 days, of the Standing Veterinary Committee and one meeting of the Standing Committee on Zootechnics. In addition, the Member States and the Commission services also meet regularly in expert, scientific, technical and working groups organized by the Commission to examine particular issues.

A system for the notification of animal diseases to the Commission and other Member States was established by Council Directive 82/894/EEC³⁸, with information transmitted electronically within 24 hours. A computerized system (ANIMO) for the notification of animal movements has also been established³⁹, with the Member State of dispatch providing the Member State of destination with advance notice of the arrival of animals, and now connects more than 2,000 local units in the 12 Member States and some 125,000 messages transmitted during the second half of 1994. The ANIMO system will be implemented in Austria, Finland and Sweden during 1995.

Work is underway to develop a further electronic information system connecting all the border inspection points in the Community, the SHIFT system⁴⁰ to ensure close and effective cooperation between the Community's external border posts and ensure effective implementation of the Community's import requirements.

Commission officials from the Office of Veterinary and Phytosanitary Inspection and Control (OICVP) regularly carry out missions in the Member States to ensure the uniform application of Community law. These missions, which are carried out in cooperation with the competent national authorities, provide a useful opportunity for exchanging information and discussing practical problems. In 1994 there were 142 missions focusing on animal health, fraud, poultry, residues and border inspection posts.

A programme of exchanges of veterinary officers between the Member States has been in place for some time, based on Article 34 of Council Decision 90/424/EEC⁴¹. In 1994 these exchanges focused on veterinary officers responsible for work in border inspection posts, and 31 exchanges took place involving all 12 Member States.

Conferences and seminars are organized both by the Member States and the Commission.

³⁷ Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters, OJ L 351, 2.12.1989, p. 34. Last amended by the Act concerning the conditions for the Accession of Austria, Finland and Sweden and adjustments to the Treaties on which the EU is founded, OJ C 241, 29.8.1994, p. 21.

³⁸ Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community, OJ L 378, 31.12.1982, p. 58. Last modified by the Act concerning the conditions for the Accession of Austria, Finland and Sweden and adjustments to the Treaties on which the EU is founded, OJ C 241, 29.8.1994, p. 21.

³⁹ Established in accordance with Article 20 of Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the establishment of the internal market, OJ N° L 224, 18.8.1990, p. 29. Last amended by the Act concerning the conditions for the Accession of Austria, Finland and Sweden and adjustments to the Treaties on which the EU is founded, OJ C 241, 29.8.1994, p. 21.

⁴⁰ Council Decision 92/438/EEC of 13 July 1992 on computerization of veterinary import procedures (SHIFT project), amending Directives 90/675/EEC, 91/496/EEC, 91/628/EEC and Decision 90/424/EEC, and repealing Decision 88/192/EEC, OJ L 243, 25.8.1992, p. 27. Last amended by the Act concerning the conditions for the Accession of Austria, Finland and Sweden and adjustments to the Treaties on which the EU is founded, OJ C 241, 29.8.1994, p. 21.

⁴¹ Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field, OJ L 224, 18.8.1990, p. 19. Last amended by Decision 93/70/EEC of 21 December 1992, OJ L 25, 2.2.1993, p. 34.

7C — Phytosanitary and other legislation relating to crop products and animal nutrition

1° Existing mechanisms for enforcement cooperation

A well developed framework of enforcement cooperation in the areas of plant health, seeds, plant breeders' rights, animal nutrition, pesticide residues, plant protection products and organic farming has existed for some time in the form of the regulatory committees which covers these sectors of activity⁴². Some of these committees have existed since the mid 1960s and others, as in the case of plant health and plant breeders' rights, since 1977 and 1994 respectively.

Apart from their legislative functions, these committees, particularly through their numerous dependent committees of experts and working groups, ensure regular and intensive exchanges of information. Fast information exchange is essential in many cases, for example where a Member State has intercepted a plant or plant product originating in a third country or in the EU which does not fulfil the EU legislative requirements. This is usually achieved through direct contacts between the Member States and the Commission. This is supplemented by the EUROPHYT system, an electronic mailing system between Member States for information exchange.

Specific cooperation exercises include the organizing of technical workshops and exchanges of officials between Member States under the KAROLUS programme (twelve had been approved by mid-November 1995). The Plant Health Inspectorate organizes seminars and training courses for Member States on plant health inspection and also participates itself in national training courses. Furthermore, the Community has arranged for Member States to cooperate in exchanging available scientific information and for the performance of research projects in the field of plant health. In the pesticides area, a seminar covering all Member States was held in 1994 and, under a new pilot project, monthly meetings of the Member States are being held to discuss specific aspects of implementation.

The committees also ensure that there is a common interpretation and application of Community legislation in these highly technical fields through discussion and exchanges of practical experience. In some areas there is a specific legislative requirement to ensure a uniform approach. For example, in the seeds area, the carrying out of Community comparative trials is designed to ensure harmonized technical methods of seed certification. Also, if necessary, the Commission will assist in interpretation of difficult pieces of legislation by issuing, for example, 'interpretative notes',.

2° Next steps

Areas of cooperation which might be improved are those relating to the exchange of officials under the KAROLUS programme (experience has shown a reluctance on the part of some Member States to accept officials due to a lack of time) and the development of the use of electronic mail transfer between Member States.

7 D — Veterinary Medicines

See section 1 B above under Pharmaceutical products

⁴² That is the Standing Committee for Seeds and Propagating Material for Agriculture, Horticulture and Forestry; Standing Committee for Plant Health; Standing Committee for Animal Feedingstuffs; Standing Committee for Propagating Materials and Plants of Fruit Genera and Species; Standing Committee for Propagating Material and Ornamental Plants; Standing Committee on Plant Variety Rights and the Standing Committee for Organic Farming.

8. Notification of technical Regulations - Directive 83/189

1° Introduction

This Directive⁴³ provides for notification to the Commission of national draft standards and technical regulations which may give rise to technical barriers within the Internal Market. This gives the other Member States and the Commission the opportunity to react to the draft regulations concerned, which may not be brought into effect until after a standstill period. It is an example of a formalized system of information exchange in which all communications pass through the Commission.

2° Existing mechanisms for enforcement cooperation

The Committee for Standards and Technical Regulations, which oversees application of the Directive, also brings together the Notifying Authorities which appoint the Notified Bodies under the New Approach directives. Until the recent meeting in July 1995 (see section 1.a)(i) above), it was also the only body in which issues relating to the application of the Toys Directive were discussed.

Electronic mail is used for summary notifications and for associated messages. A project to increase the use of E-mail and to establish appropriate databases is at the feasibility study stage under the IDA programme (see section 22).

3° Needs

To be determined by the study.

9. Customs

1° Introduction

Customs is an area where administrative cooperation was implemented very quickly. As early as 1968 the Commission was trying to harmonize legislation, mainly through directives. Directives have been progressively replaced by sectoral regulations, which are more binding and more effective in achieving legislative harmonization. It became clear, however, that this inconsistency in the legal form of the texts was far from making them easier to implement. The Commission thus undertook to bring the existing rules together in a customs code, which came into effect when the single market was completed. Customs administrations and economic operators now have to deal with legislation which is accessible, precise and consistent. This is an indispensable condition for the operation of the single market.

2° Existing mechanisms: the "Customs 2000" programme, a new challenge for customs in the European Union

If a single market without internal frontiers is to function properly, any customs checks carried out in it must be uniform across the various Member States.

The Commission has thus proposed a number of projects in preparation for customs work into the next century, on a basis of partnership with the Member States. The aim in each case is to enable customs to watch and control the Community's external frontier, putting existing legislation on a firmer footing by developing consistent practices. These measures all depend on administrative cooperation of a very active kind.

The measures under way include the following:

(a) adoption of new working methods

Efforts are afoot at the Commission to spread the use of risk analysis techniques, whereby physical or documentary inspections can be targeted, by working out in conjunction with the Member States guidelines enabling them to become aware of all the methods at present in use in the Union.

Similar efforts will be devoted to audit techniques, the aim of which is to permit thorough inspection of the accounts and management of enterprises, including those with establishments in more than one country.

(b) customs penalties

In partnership with the Member States the Commission is looking into this field, with the aim of avoiding any distortions of competition which economic operators might be liable to.

(c) evaluation of results

Monitoring visits are being paid to Member States, by joint teams of national officials from other Member States and Commission staff. They enable national officials to acquaint themselves directly with the working methods of other customs administrations. The aim is to ensure the wider adoption of those practices which are identified as most effective.

(d) training

A specific training programme for officials from the Member States (the Matthaeus programme) was set up by Council Decision in 1991⁴⁴. It provides for exchanges of customs officials from the Member States and seminars on specific customs legislation topics. It also aims to develop shared training material.

(e) information technology

The Commission and the Member States support the idea of a global strategy to guide the future development of information technology in customs procedures. It will be based on using existing systems and developing links between them. It also aims to use businesses' computer systems.

3° Impediments

There is currently an institutional obstacle to these measures, whose aim is the consistent implementation of uniform legislation. Most customs cooperation is a matter of Community competence, but unharmonized fields, such as weapons, drugs and nuclear military material, are covered by Title VI of the Maastricht Treaty (Article K.1(8)). This means that there are difficulties in the interface between these provisions and Community law.

4° Next steps

The Commission will be carrying on with the programme begun in 1994, in order to put it on a firmer footing and give it more concrete form. The measures described above could be expanded and developed. The main aim is that customs administrations should get to know each other and work together spontaneously and naturally, with the aim of ensuring greater equality of treatment between operators, through inspection being carried out in a consistent manner.

⁴⁴ Council Decision 91/341/EEC of 20 June 1991, OJ No L 187, 13.7.1991, p. 41

10 Taxation

10 A — Direct Taxation

1° Introduction

Directive 77/799/EEC on mutual assistance in the field of direct and indirect taxation provides a framework under which Member States provide mutual assistance so as to combat international tax evasion and avoidance. It is largely concerned with exchange of information.

2° Existing mechanisms for enforcement cooperation

An on-going programme of meetings between direct tax officials of Member States to improve the quantity and quality of information exchange under the Directive was begun in 1993. The working group concerned achieved its first results in 1994 when common guidelines on the conduct of exchange of information involving specific requests were agreed. The group also established a code of practice on the "turnaround" times that Member States should aim to meet when responding to requests received. By pooling simple statistics on how far agreed standards are met, the group will monitor progress, and review them as necessary in the future.

3° Needs

To increase and improve the use made of the existing instruments

4° Impediments

Different levels of tax and bank secrecy in different Member States.

5° Next steps

The working group will examine how equivalent improvements might be achieved in the field of exchange of information involving "automatic" or "spontaneous" means.

10 B — Indirect Taxation

1° Introduction

The abolition of border formalities on 1 January 1993 placed a premium on enforcement cooperation between national tax control authorities. The VAT Information Exchange System (VIES) was thus set up between them through Regulation 218/92. Similarly, Directive 92/12 established a Committee on Excise and a System of Exchange of Excise Data (SEED) Certain VAT data is now stored and transmitted electronically between Member States, and excise data by diskette.

The Regulation also provided for the establishment of a network of Central Liaison Offices and the Standing Committee on Administrative Cooperation (SCAC), which is also foreseen in Directive 77/799 on mutual assistance in the field of direct and indirect taxation. The Commission runs the telematic network, maintains and distributes a directory of the Offices and manages the SCAC and the Excise Committee. It provides a framework for future development of cooperation in

partnership with the Member States in the light of shared experience and a common perception of one another's needs.

2° Existing mechanisms for enforcement cooperation

Council Decision 93/588 set up the Matthaeus-Tax programme, which provides for exchanges of indirect tax officials between administrations and the holding of training seminars for enforcement and training officials. Up to 100 officials are exchanged each year and 10 or more seminars are held. The decision also provides for common training programmes to be implemented in each Member State.

For VAT control purposes, the administrations need to be able to identify traders who are making intra-Community acquisitions to ensure that they are correctly accounting for the tax. Data from quarterly statements by traders is exchanged between administrations through the VIES for this purpose. The VIES also enables VAT identification numbers to be checked across internal borders, whilst for excise duties, the SEED fulfils the same function. Further information can be requested, under both Regulation 218/92 and Directive 77/799. More than 1 400 such requests for further information were handled during 1994. For excise, similar data is exchanged under the movement verification system established in accordance with Article 19(6) of Directive 92/12/EEC.

The VAT Committee provided for in Article 29 of the 6th VAT Directive and the Committee on Excise duties mentioned above ensure the common interpretation of Community Law on indirect taxation. Valuable input is provided by the Advisory Committee on Customs Matters and Indirect Taxation and a number of ad hoc bodies.

The Commission distributes a guide on VAT arrangements in each Member State, recently updated to include the new Member States. It has also initiated and financed experiments on the coordinated control by several Member States of multinational enterprises and other enterprises operating in intra-Community trade.

3° Impediments

These are few, thanks partly to the Central Liaison Offices. The Commission, the SCAC and the Committee on Excise duties keep watch on those still caused by differences in legislation and methods.

4° Next steps

The Commission proposes to build on the already high level of enforcement cooperation in this sector and, in addition to its work on the exchange of information, is seeking to improve mutual assistance in the recovery of tax debts by examining the use of existing Community arrangements and reviewing the adequacy of the legislation.

The adequacy of existing messaging systems will also be reviewed, for example the present exchange of excise data from national databases by means of diskettes will be replaced by an on-line system. The Commission will argue for adequate budget to finance this, the VIES and the Matthaeus-Tax programme.

11. Drug Precursors

1° Introduction

Regulation 3677/90 as amended was adopted to implement Article 12 of the 1988 UN Convention against Illicit Drugs Traffic, to which the Community has become a Contracting Party. The amendments introduced by Reg. 900/92 reflect the results of the G7 Chemical Action Task Force (CATF) established by the 1990 Houston Summit, in the work of which the Commission and seven Member States participated.

2° Existing mechanisms for enforcement cooperation

Information exchange takes place via the SCENT E-mail network which operates on some 300 terminals in all Member States. The network is open to all authorities competent under the above Regulation. Administrations not yet connected are being served via fax or telex.

(a) Exchanges between Member States' officials

Exchanges between enforcement officials are planned in 1995 under the Matthaesus (customs) and Karolus (other branches) programmes. In addition, 1-month traineeships at the Commission will soon be offered to Member States' officials (quite a number of applications have already been received).

(b) Training programmes:

Annual seminars have been held since 1994, partially financed under the Matthaesus programme; it is suggested that more specialized events be conducted, each aimed at a specific group of officials (investigators, licensing officials, etc.).

(c) Other

The smooth implementation of the rules is monitored at the periodic meetings of the Drugs Precursors Committee. Cases of diversion established or suspected have to be reported to the Commission as well as other elements that concern gaps or shortcomings in the provisions. Instances of divergent implementation are examined by the Committee with a view to finding a solution shared by all delegations. Committee rulings are established and circulated to administrations as "Agreed Opinions".

In addition to contacts through the Committee, officials from the Member States regularly participate as trainers in external programmes in favour of third countries (e.g. a precursors training programme under PHARE; seminars for CIS, Middle Eastern, ASEAN etc. countries) which offer continuous opportunities for contact and feedback.

3° Needs

Competent authorities have to consult each other with regard to all relevant aspects of the matter (issue of licences, export authorizations and in particular, anti-fraud cooperation). Regulation 3677/90 refers to the application, *mutatis mutandis*, of Reg. 1468/81, as an established tool of administrative cooperation in the field of customs and agriculture. The Commission depends on a continuous information flow to fulfil its role as coordinator in anti-fraud matters, reporting to international organizations such as the United Nations.

4° Impediments

Certain difficulties may stem from a lack of coordination with other areas managing similar forms of export controls (chemical weapons etc.), and the sharp contrast between drugs precursors being subject to Community procedures and the remaining field of drugs cooperation involving cooperation under Title VI of the Treaty on European Union.

5° Next steps

Maintaining the current resource and action level would certainly help to ensure a continuous growth in the efficiency of cooperation in this field. It would be desirable if the Commission and Member States could overcome pragmatically the unproductive gap between activities based on the EC Treaty and those under Title VI TEU.

12. Cultural Goods

1° Introduction

The Community has adopted two main instruments in the field of protecting cultural goods, in order to do away with checks on goods at internal frontiers: the Regulation on the export of cultural goods⁴⁵ and the Return Directive⁴⁶.

2° Existing mechanisms for enforcement cooperation

There can be no question of any return arrangements without cooperation between the Member States (for instance, to find out where unlawfully removed goods now are and who is in possession of them). The Directive thus provides for the cooperation which is indispensable if the mechanism for return is to operate properly.

Powers regarding the protection of cultural goods are spread among many different authorities in each Member State, so the Directive lays down that each country is to designate one or more central authorities (depending on the particular structures of the Member State, which may be a federal one) to carry out the functions covered by the Directive.

These central authorities serve mainly as contact points. They cooperate with each other and facilitate consultation among the competent authorities of the Member States.

The Directive lays down that Member States are to inform the Commission of the central authorities they designate and that the Commission is to publish a list of them in the Official Journal.

The Regulation also provides that there is to be cooperation between the authorities responsible for controls on cultural goods being exported and the central authorities referred to here.

3° Needs

The "general" cooperation on protection of national treasures envisaged by the Council and falling within the competence of the Member States has not so far been embarked upon. The Council's working group on drugs and organized crime has started its examination of initiatives in police cooperation against illegal traffic in works of art.

4° Impediments

Nine Member States were to have transposed the Directive by 15 December 1993, Belgium, Germany and the Netherlands by 15 March 1994, and Austria, Finland and Sweden by 1 January 1995.

By October 1995, it had been transposed only by Denmark, Spain, France, Ireland, the Netherlands, Finland, Sweden and the United Kingdom. Of these eight, only Finland, Ireland, Sweden and the United Kingdom had informed the Commission of their central authorities.

5° Next steps

Those Member States which have not yet done so should transpose the Directive as soon as possible and let the Commission know who their central authorities are, indicating whether they are the same contact points notified under either the Regulation or the Council Resolution of 16 June 1994 on administrative cooperation.

⁴⁵ Council Regulation (EEC) No 3911/92 of 9 December 1992 on the export of cultural goods, OJ No L 395, 31.12.1992, p. 1

⁴⁶ Council Directive 93/7/EEC of 15 March 1993 on the return of cultural objects unlawfully removed from the territory of a Member State, OJ No L 74, 27.3.1993, p. 29

13. Freedom of Establishment

Recognition of diplomas

1° Introduction

In the recognition of diplomas, there are already several examples of administrative cooperation playing a very important role in the proper implementation of the Directives.

2° Existing mechanisms for enforcement cooperation

The Committee of Senior Officials on Public Health, set up in 1975, is made up of Member States' senior officials with direct responsibility for public health. Its job is to discuss and where possible solve problems arising in the implementation of the Directives concerning doctors, dentists, nurses and midwives.

Ad hoc working parties have been set up by the Commission to cover the Directives on architects and veterinarians. Like the Pharmaceutical Committee, whose scope was extended to include pharmacists by Directives 85/432 and 85/433, they do the same work as the Committee on Public Health in their own specific areas.

Directives 89/48/EEC and 92/51/EEC on a general system for the recognition of diplomas also set up a system of administrative cooperation between the Member States and the Commission. Under them, each Member State has to appoint a coordinator for recognition of diplomas. The coordinators meet five times a year with the Commission, to discuss problems in implementing these Directives. Their discussions provide guidance for the Member States in uniform interpretation of the Directives as regards certain more sensitive areas. Contacts between coordinators and between them and Commission officials have enabled many specific problems to be resolved. The group has also helped in drawing up the vade mecum to the general system and the user's guide, intended for the use of private citizens.

3° Next steps

Improving cooperation involves above all constant efforts to build mutual confidence in daily work. This will be continued in the committees and groups mentioned above (and the seven others which also include expert members from the universities and the professions).

Efforts will continue to develop the use of electronic mail, where this is justified, and to improve statistics.

14. Company Law

In general, for problems in the company law areas the partners of the Commission are the representatives of the ministries of Justice. As far as the accounting area is concerned, the partners come from the ministries of Justice or the economics or finance ministries.

14 A — Accounting

1° Introduction

With the adoption of the Fourth Directive in 1978 a "Contact Committee for the Accounting Directive " was set up. This Committee is composed of representatives of the Member States and of the Commission. The chairman is a representative of the Commission.

2° Existing mechanisms for enforcement cooperation

The functions of the Committee are:

- to facilitate harmonized application of the Accounting Directives through regular meetings dealing in particular with practical problems arising in connection with its application;
- to advise the Commission, if necessary, on additions or amendments to these Directives.

The Committee is convened (normally twice a year) by the chairman either on his own initiative or at the request of one of its members. The points of the agenda are largely influenced by the representatives of the Member States.

The outcome of discussions on accounting problems are laid down in the meeting report. In 1990, a brochure summarizing some of the conclusions was published by the Commission.

There is agreement that the Contact Committee is the appropriate body to "play a leading role in the practical organization of cooperation between the competent administrations of the Member States and the Commission departments, primarily in the framework of existing bodies and committees", as called for in the Resolution.

As the accounting rules are very much influenced by national standard setting bodies, an Accounting Advisory Forum, representing the main parties involved in accounting in the EU, was set up. This body advises the Commission on technical accounting matters and possible ways to facilitate further harmonization.

14 B — European Economic Interest Grouping (EEIG)

1° Introduction

A Contact Committee was set up under the Regulation on the European Economic Interest Grouping⁴⁷ adopted on 25 July 1985.

⁴⁷ Council Regulation (EEC) No 2137/85 of 25 July 1985 on the European Economic Interest Grouping, OJ L 199, 31.7.1985, p.1

2° Existing mechanisms for enforcement cooperation

The functions of the Committee are to facilitate the application of the Regulation through regular consultation dealing in particular with practical problems arising in connection with its application and to advise the Commission, if necessary, on additions or amendments to the Regulation.

3° Next steps

It is hoped that the Contact Committee may act as a means of collating information on EEIGs registered in individual Member States, which would assist in the maintenance by the Commission of a database of existing EEIGs.

15. Insurance, Banks, Securities

15 A — Insurance Sector

1° Introduction

In the insurance sector, administrative cooperation has always been considered necessary to ensure the proper enforcement of EEC legislation throughout the Community. EEC Insurance Directives already lay down close cooperation among the competent insurance supervisory authorities. The whole system of the "European passport" is built on such cooperation. Cooperation is also required between Member States and the Commission in order to ensure the correct implementation of these Directives.

2° Existing mechanisms for enforcement cooperation

Two fora carry out the enforcement cooperation in the insurance sector: the Conference of Insurance Supervisory Authorities (of the Member States of the EU) and the Insurance Committee.

The Conference was set up in 1957 by Member States. The Commission has observer status. The Conference discusses problems relating to insurance supervision (*i.e.* solvency of insurance undertakings). The Conference has also laid down protocols for collaboration between the competent authorities to facilitate the practical implementation of the insurance directives.

The Insurance Committee (IC), was created by Directive 91/675/EEC. Apart from its role of assisting the Commission in the use of its implementing powers, the Insurance Committee may examine any particular question pertaining to the insurance sector as well as the application of the insurance directives. A number of questions concerning insurance problems have already been discussed by the IC (insurance groups, border lines between social security and insurance, interpretation of insurance directives, etc.)

An *ad hoc* Interpretation Group was created in 1994 to examine interpretative questions arising from EU legislation on insurance. The group, composed of representatives of Member States' supervisory authorities, is chaired by the Commission. The Interpretation Group reports to the Insurance Committee, which may convene to discuss the interpretation to be given to a particular provision of EEC legislation. Two meetings have taken place in 1995.

The Insurance Committee, under its "comitology" powers, may also take decisions to clarify the definition of the insurance directives.

The KAROLUS programme provides an opportunity for the exchange of officials of national competent authorities. The first conclusion of these exchanges appears to be positive.

3° Needs

Cooperation between Member States and Member States and the Commission is essential to ensure the smooth application of the "single licence" system and the home country supervisory regime in the Community.

The Third Insurance Directives also provide for on-the-spot verification by the Home Member State of the branch of an insurance undertaking. The competent authorities of the Host Member State must cooperate with the Home Member State to facilitate this verification of the branch. They may also take part in this verification exercise.

Interpretative Communications could be used to make clear the Commission's position on particular and sensitive points. This is the case in the management and custodian activities of pension funds. A Communication on the management of assets held by pension funds as well as the investment of these assets was published by the Commission in December 1994.

4° Next steps

Besides participation by national officials in Karolus, the participation by Commission officials in specific training programmes on insurance and financial services aspects would be useful. Training periods with supervisors and in insurance companies are also seen as necessary to enable the Commission to carry out its tasks.

The Commission has started discussions with Member States to set up a pilot programme for an electronic network to enable the exchange of messages and information on the supervision of insurance undertakings between Member States' competent authorities (*EDENIS Electronic data exchange network in insurance*). This network could ease cooperation between competent authorities. The objective was to make the system operative during the second half of 1995. Unfortunately, budgetary constraints have meant that it has been postponed for the time being.

However, it is felt that some kind of electronic network will be necessary to improve enforcement cooperation, make the exchange of information between administrations easier and quicker and make for a more efficient supervision of the insurance industry in the internal market.

15 B — Banks

1° Introduction

The second Banking Directive, 89/646/EEC of 15 December 1989, has been in force since 1 January 1993. Among its provisions this directive introduced a single "passport" or licence for credit institutions, which is recognized throughout the Union and is backed up by innovative machinery for notification and cooperation, being based on supervision by the authorities of the country of registration for overall solvency and by the host country for liquidity of branches on its territory.

2° Existing mechanisms for enforcement cooperation

There has been cooperation with the Member States in the banking field, at institutional level, since 1979, when the Banking Advisory Committee was set up by the first coordinating directive (77/780/EEC). Another form of cooperation takes place in the Contact Group of the banking supervisory authorities of the Member States, which was not set up by a Community directive but whose existence was recognized by Community instruments, and in which the Commission's participates. The Central Bank Governors of the European Community hold cooperation meetings without the Commission in the Subcommittee on Banking Supervision of the European Monetary Institute.

These various bodies examine the problems in the single banking market with a view to working out solutions that can be the subject of national measures, or to recommending to the Commission solutions which require new proposals for Council or Commission directives in accordance with the new committee procedures.

The Commission has also received many bilateral memoranda of understanding, which the majority of Member States have concluded with a view to implementing the new procedures introduced by the second Directive.

The Commission has set up the Working Party on the Implementation of the Banking Directives (WPIBD), whose purpose is to examine and, as appropriate, resolve all the problems of interpretation which the Member States encounter when applying the directives. If the Working Party agrees on a common interpretation, the Commission undertakes to publish it. If there is no agreement, the problem is referred to the Banking Advisory Committee (BAC), which delivers an opinion. If the Committee reaches agreement the Commission publishes the interpretation; if it does not, the Commission has the right to draw the conclusions necessary. The Commission has published a draft communication on the concepts of freedom to provide services and the interest of the general good, interpretation of which has been under discussion in the WPIBD and the BAC⁴⁸.

3° Needs

The home and host countries need to exchange prudential and other information, especially if there is doubt as to whether the institution still complies with the criteria for authorization.

4° Next steps

A recently adopted Council Directive⁴⁹ extends the arrangements for the exchange of information between supervisory authorities belonging to different categories and requires external auditors to notify the supervisory authorities of any circumstances likely to undermine the stability of the institutions whose accounts they audit.

In the light of contributions received in response to its draft communication mentioned above, the Commission will consider publication of an interpretative communication enabling economic operators and the Member States to determine the stance that the Commission would be likely to adopt on these questions in the event of a particular problem being brought to its attention.

15 C — Securities

1° Introduction

Many directives already adopted in the securities markets field, for example the 1979 directive on stock exchange listing conditions, provide for cooperation between the competent authorities in different Member States, notably as regards the exchange of information. Such information exchanges are covered by a professional secrecy obligation.

In addition Member States supervisors meet at biannual meetings organized by the Commission (High Level Securities Supervisors Committee) and on an informal ad hoc basis without Commission participation. Furthermore, the Commission has adopted a proposal for a Directive on the

⁴⁸ OJ C 291,4.11.1995, p. 7.

⁴⁹ European Parliament and Council Directive 95/26/EC of 29 June 1995 amending Directives 77/780/EEC and 89/646/EEC in the field of credit institutions, Directives 73/239/EEC and 92/49/EEC in the field of non-life insurance, Directives 79/267/EEC and 92/96/EEC in the field of life assurance, Directive 93/22/EEC in the field of investment firms and Directive 85/611/EEC in the field of undertakings for collective investment in transferable securities (Ucits), with a view to reinforcing prudential supervision, OJ L 168, 18.7.1995, p. 7

setting up of the Securities Committee⁵⁰, which would replace the High Level Securities Supervisors Committee.

2° Existing mechanisms for enforcement cooperation

In the securities markets field cooperation is being given practical effect by the drawing up of mutual cooperation agreements ("Memoranda of understanding) between supervisors whose countries have significant amounts of trading volume between them. These agreements were initially entered into between some European Supervisors and US and Japanese regulators, but are now becoming more common as regards contacts within Europe.

3° Needs

As securities trading is essentially an international activity, the more so as information technology permits greater ease of communication, effective regulation of market participants depends crucially on cooperation between supervisors in the enforcement of their respective national rules. This is particularly evident in the case of insider trading, where an insider can use the securities market of another country to carry out an illegal trade in the hope of non-detection by the home country supervisors. The Commission does not play an active part in this exchange of information between supervisors, because the Commission has no direct supervisory role to play.

Following the adoption in 1993 of the Investment Services and Capital Adequacy directives the Commission has convened a certain number of informal interpretation meetings on both directives in order to discuss particular problems encountered by Member States in the course of the implementation process.

4° Next steps

The Commission should monitor how effectively the cooperation provisions of the securities markets directives are working in practice, particularly when there is a sharing of supervisory responsibility between home and host Member State supervisors and the Directive setting up the Securities Committee should be adopted as soon as possible.

⁵⁰ COM (95) 360 final of 17 July 1995

16. Intellectual Property

1° Introduction

Practical implementation of Community legislation concerning industrial property is a matter for Member States' patent offices, most of which are independent of any national ministry. They deal with patents, trade marks, designs and models generally, and also any utility models. A high degree of coordination between the policies of Member States, through the European Patent Office in Munich and the Office for Harmonization in the Internal Market in Alicante.

2° Existing mechanisms for implementation cooperation

As regards patents, the meetings of the Administrative Council and of Heads of delegation at the European Patent Office (Munich) provide the opportunity for regular exchanges of views between representatives of the Commission and of the Member States, including as regards developments in national legislation. The same meetings also enable ratification of the Luxembourg Convention on the Community patent to be monitored. The European Patent Office also provides the secretariat for a special body responsible for setting up the Community patent, called the Community Patent Interim Committee.

A meeting of national experts organized by the Commission in January 1995 allowed a discussion of a number of problems in the interpretation of Regulation 1768/92 concerning the creation of a supplementary protection certificate for medicinal products, on which joint guidelines were worked out.

As regards trade marks, since the adoption of Regulation 40/94 on the Community trade mark, meetings of the Administrative Council of the Office for Harmonization in the Internal Market (trade marks, designs and models) have been providing the opportunity for meetings with Member States' officials. These meetings discuss matters concerning the setting-up of the Alicante office and also monitor certain aspects of national trade marks.

There is appropriate coordination for meetings of the governing bodies of the World Intellectual Property Organization (WIPO) in September each year and of expert committees looking at specific aspects of intellectual property. Thanks to such coordination, the Presidency is frequently able to speak for all 15 Member States.

As regards copyright and neighbouring rights, there are contacts in the Council's Working Party of Intellectual Property Attachés, where positions are coordinated for meetings at WIPO. Discussions within the Council of Europe and UNESCO on copyright matters also provide the opportunity for many meetings between Commission and Member State representatives.

3° Next steps

The Commission plans to continue and if necessary step up its contacts with Member States' experts.

17. Broadcasting

1° Introduction

All the Member States have reported their national measures transposing Directive 89/552. The Commission has decided to initiate infringement procedures against most of them. The national legislation of the new Member States is currently being scrutinized. Most of the problems (mistaken interpretation, ambiguous drafting) seem to be nearing solution. The points at issue vary greatly from one Member State to another and a strengthened coordination procedure is unlikely to provide a solution for them.

2° Existing mechanisms

To monitor this Directive, there is an ad hoc group of representatives of Member States set up by the Commission, to discuss problems of interpretation or implementation encountered by the Member States. This group has been very useful in facilitating implementation of the Directive and will continue to play this role both in monitoring implementation of the present Directive and implementing the new one when it is adopted.

3° Needs

Some Member States have said that it would be useful to have a formal working group (composed of regulatory bodies) with the dual task of formulating a joint approach to problems concerning public morality (pornography, violence, collaboration in the viewing of films etc. and ensuring regular exchange of information on broadcasting bodies in order to avoid gaps or overlaps between the competence of Member States.

4° Next steps

The Council, at its meeting held on 20 November 1995 for the purpose of revising the Directive, arrived at a political agreement, part of which involved the establishment of a contact committee.

18. Transport

1° Existing mechanisms

In transport, and particularly in road and air transport, cooperation either between the Member States or between them and the Commission is expressly provided for in some regulations and directives.

The cooperation networks thus set up are still far from being effective in all areas, but some of them are operating fairly well, for example, international passenger bus transport, road passenger and goods cabotage, crisis measures in road transport of goods, taxation of road transport, mutual recognition of boatmasters' certificates (inland waterways), access for Community air carriers to intra-Community air routes. Ad hoc meetings are organized for this purpose.

Other networks have been provided for in the legislation but are not operating well. In certain areas no such networks are provided for.

Under the Karolus programme, a number of exchanges have taken place between national officials responsible for inspection work in the implementation of legislation concerning road transport and in the field of shipping.

Part II

Other areas

19. Social Policy

19 A — Social Security for Migrant Workers

1° Introduction

In accordance with the provisions of Articles 48 - 51 of the Treaty on free movement for workers, Council Regulation 1408/71⁵¹ lays down provisions for the coordination of national social security schemes. Detailed provisions on the implementation of Regulation (EEC) 1408/71, including the institutions responsible, are laid down in Regulation 574/72 of 21 March 1972.

2° Existing mechanisms for enforcement cooperation

An "Administrative Commission on Social Security for Migrant Workers" is set up by virtue of the provisions of Regulation 1408/7. This Administrative Commission, made up of Member State representatives has a number of tasks including dealing "with all administrative questions and questions of interpretation arising from the provisions of the Regulation." In cases where administrative problems arise due to lack of enforcement of the provisions of the Regulation, the subjects are discussed in the Administrative Commission and solutions are found. The Secretariat of the Administrative Commission is often contacted by individuals claiming that social security institutions have failed to recognize their entitlement to benefits under the provisions of Regulation 1408/71. Solutions are found in collaboration with representatives of the Member States in the Administrative Commission.

Within the Community, there are thousands of social security institutions implementing Regulation 1408/71. The Administrative Commission has elaborated a number of model forms that structure the flow of information between institutions in the Member States.

In 1991, the Administrative Commission set up the TESS Working Party (Telematics for Social Security) which implements the TESS Programme: Development of Telematic Services for the Coordination of European Social Security Schemes. The TESS Working Party analyses the needs of the social security institutions in terms of exchange of information and defines appropriate solutions for improvement and modernization.

Once it has dealt with a question of interpretation of Regulation (EEC) 1408/71 or 574/72, the Administrative Commission formalizes its findings in Decisions or Recommendations which are published in the Official Journal.

Within the TESS framework a glossary of "Social Security Terms" is being developed to support the future telematic exchange of information.

The Secretariat of the Administrative Commission within the Commission organizes regular seminars on various subjects relating to the implementation of Regulation 1408/71. In 1994 a guide was published, describing the functioning of the Regulation in a language which is easily accessible for the general public and introducing the social security schemes in the Member States.

⁵¹ Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, OJ L 149, 5.7.71, p.2

19 B — Labour Inspection

1° Introduction

Since 1982, on the initiative of the Commission, a Committee of Senior Labour Inspectors (SLIC) has held regular meetings with the aim of improving cooperation between Member States and the Commission and of encouraging the effective and consistent enforcement of European legislation in the Member States. The Committee consists of two high-ranking representatives of the labour inspectorates in each of the Member States.

From the start SLIC has been both a forum of close collaboration between national experts from the Member States and the Commission to exchange information and a network of relevant officials to assist the achievement of effective enforcement of Community social legislation.

By decision of the Commission on 12 July 1995, the SLIC was established as an official Committee.

2° Existing mechanisms for enforcement cooperation

The SLIC has established a network of national correspondents - labour inspection - for the rapid exchange of information. This network is being used to exchange information about enforcement of Community law on the internal market and, among others, the enforcement of the Machinery Directive.

The SLIC has defined common principles of labour inspection in the field of health and safety at work and is fostering the development of methods of assessing national systems of inspection in relation to these principles (the first pilot evaluation is now being carried out in the Netherlands).

One of the main activities of the SLIC is the exchange of inspectors between Member States.

Over the years, nearly 100 inspectors have visited another European country to study a topic of particular interest to their own country. Through this activity mutual knowledge about enforcement experiences is being promoted.

Two "European Sessions" to exchange information on methods of inspection in specific sectors, involving inspectors from four different Member States, have been completed since the beginning of 1990s, in the construction and agricultural sectors respectively. A third will be launched at the next plenary meeting of SLIC. The sector will be the car industry and its subcontractors.

One of the documents resulting from the work of SLIC is a training module for labour inspectors on the EU and health and safety at work. This training module has been used as the basic material for training programmes for labour inspectors in all Member States

3° Needs

The necessary human and budgetary resources should be made available to promote the further work of the Committee as expressed in its three-year programme.

4° Impediments

It is very important that the necessary communication resources, such as interpretation and translation, should be provided to support the work of the SLIC in its task towards effective and consistent enforcement of Community health and safety legislation.

20. Public Administration

1° Introduction

Although under the Treaties public administration is not a matter of Union competence, the progress of the building of Europe, especially in the internal market field, requires ever closer cooperation between administrations. Meetings of Civil Service Heads - 24 in all so far - have thus become the forum for discussing problems of common interest, with implications for the building of Europe.

2° Existing mechanisms

At the Nancy Ministerial Conference in February 1995, the Civil Service Heads were given the task of seeking overall, balanced solutions to remove the obstacles in the way of opening up public service employment to Community nationals and improving coordination in the training of national officials in European matters. At their most recent meeting in Paris in early May 1995, the Civil Service Heads decided to:

- set up two working groups, one to examine access to public service employment, the other to deal with pension regimes for officials. They should present their conclusions in the first half of 1996;
- organize two meetings of national schools and institutes of administration, in June and October 1995.

Within the limits of their powers, which vary greatly from one country to another, the Civil Service Heads also help in supporting the programmes for exchanges of national officials, including the Karolus Programme.

3° Needs

Recurrent problems in the development of administrative cooperation typically concern **information** - its real-time flow between Community, national, regional and/or local administrations, and between administrations in different countries - and the **training** of national, regional and local officials in European matters.

These matters are of particular concern to regional and local administrations, especially as the Maastricht Treaty gives greater prominence to the regional dimension in the building of Europe. The associations of "préfets" are aware of what is at stake and have spontaneously taken the initiative of calling together "préfets" and their equivalents in the other countries of the Union to size up the problem and begin tackling it.

21. Competition

1° Introduction

There has from the outset been cooperation with national competition authorities in the antitrust field (see Regulation 17/62, the first regulation implementing Articles 85 and 86 of the EC Treaty) and on mergers (see Regulation 4064/89). Procedures in these fields have to be carried on "in close and constant liaison" with those authorities.

The Directorate-General for Competition is seeking to reinforce implementation of Articles 85 and 86 by national authorities. The ways and means of achieving this were covered in a report and conclusions approved by the heads of cooperation departments in September 1994. It is envisaged that the Commission will be asked to adopt, before the end of this year, a communication on cooperation with those authorities.

This communication will match the existing one on cooperation with national courts in applying the same articles, published in February 1993⁵².

2° Existing mechanisms for enforcement cooperation

Exchanges of officials are taking place between Member States' competition authorities (Bundeskartellamt, Office of Fair Trading, etc.). The Commission also has national experts from these authorities detached to it.

Checks on undertakings suspected of infringing competition rules are carried out jointly by officials from the Commission and from national competition authorities⁵².

In addition to receiving detached national experts, which enables them to get to know its aims and methods, DG IV also receives national officials for short periods of training.

Seminars and workshops take place frequently, and the heads of the Member States' competition departments meet periodically. Meetings of national experts are organized on all draft legislation and para-legal texts (communications) which concern the single market.

Discussions are also under way on decentralized enforcement of Articles 85 and 86. A recent conference, the European Competition Forum, was the first one to be open not only to representatives of national authorities but also to members of the judiciary specializing in competition matters.

3° Needs

Expanding the decentralized implementation of Articles 85 and 86 will require new procedures to be developed, and some work has already been carried out on this. These procedures should not require amendments to the legislation. The growing extent to which Community law is to be implemented by national authorities - and this is something which is to be encouraged - requires the Commission to be kept informed quickly and fully. The legislation does not at present provide for this. Computerized exchange of information could speed up the collection of information. There is a project called Fourcom (DG IV Communication), financed by the IDA programme, with one pilot application to be launched this year.

Uniform interpretation of Community competition law, especially Articles 85 and 86, requires that only cases of obvious infringement whose effects are restricted largely to one Member State should be dealt with by national authorities. This excludes concerted practices which fall under Article 85(1) but might be exempt under Article 85(3)⁵².

⁵² As regards mergers, the question does not arise. Above the thresholds laid down in Regulation 4064/89, the Community basically has sole competence. Up to these thresholds, it is the Member States alone which are responsible. The Commission also has exclusive competence in implementing the provisions of the ECSC Treaty (Articles 65 and 66) concerning competition.

22. Telematic Networks between Administrations (TNA / IDA)

1° Introduction

By 1982, well before the Internal Market Programme was launched, the Council had already adopted decisions on establishing computer links between the Community institutions and those of the Member States. The initial focus was on customs and agricultural cooperation, with a study⁵³, which led to the CADDIA programme (Cooperation in Automation of Data and Documentation for Imports/Exports and Agriculture)⁵⁴. The Council also decided to set up a Community inter-institutional integrated information system (INSIS) which would "make it possible to use new electronic technologies for exchanges of information between the administrations of the Community institutions and the Member States"⁵⁵, and which, *inter alia*, provided the Commission's own electronic mail (E-mail) backbone.

In the context of the 1992 programme it became clear that these links had to be developed to the full to enable the Internal Market to be managed effectively. The third and fourth R&D framework programmes both included studies into telematics networks between administrations. The European Nervous System (ENS) programme is part of a specific research and development programme implementing these⁵⁶. For the development of projects beyond the pre-competitive stage into fully operational systems with the specific aim of furthering management of the Internal Market, the Commission proposed in 1993 both guidelines and a multiannual Community programme to support the implementation of trans-European networks for interchange of data between administrations (IDA)⁵⁷. A single Council Decision, on the multiannual programme only, was adopted on 6 November 1995⁵⁸. This provides funding for projects, some of which are already running.

2° Existing cooperation using telematic networks

The CADDIA programme has assisted the development of the Customs Information System (CIS) and the SHIFT system (see sections 7(a) and 9 above on veterinary controls and customs). The SIMAP project, under IDA, should result in electronic tendering becoming available for Europe-wide public procurement (section 2 above). The Social Security Network (SOSENET) has been transferred from ENS to IDA as it becomes operational. Members of a number of committees, including the Internal Market Advisory Committee, have already received IDA funding for

⁵³ 77/619/EEC: Council Decision of 27 September 1977 instituting a study of informatic systems for the processing of data on imports/exports and on the management and financial control of agricultural market organizations, OJ L 255, 6.10.1977, p. 32

⁵⁴ Council Decision No 82/607/EEC of 28 July 1982 concerning the coordination of the actions of the Member States and the Commission related to activities preparatory to a long-term programme for the use of telematics for Community information systems concerned with imports/exports and the management and financial control of agricultural market organizations, OJ L 247, 23.8.1982, p.25; Council Decision No 85/214/EEC of 26 March 1985 concerning the coordination of the activities of the Member States and the Commission related to the implementation of a long-term programme for the use of telematics for Community information systems concerned with imports/exports and the management and financial control of agricultural market organizations, OJ L 96, 3.4.1985, p. 35.

⁵⁵ Council Decision No 82/869/EEC of 13 December 1982 relating to the coordination of the activities of the Member States and Community institutions with a view to assessing the need for, and preparing proposals for setting up, a Community inter-institutional information system OJ L 368, 28.12.82, p. 40

⁵⁶ Council Decision 91/353/EEC of 7 June 1991 adopting a specific programme of research and technological development in the field of telematic systems in areas of general interest (1990 to 1994), OJ L 192, 16.7.1991, p. 18; Council Decision 94/801/EC of 23 November 1994 adopting a specific programme for research and technological development, including demonstration in the field of telematics applications of common interest (1994 to 1998), OJ L 334, 22.12.1994, p. 1

⁵⁷ COM(93) 69 final, 12.03.1993, OJ C 105, 16.4.1993, pp. 10 and 12

⁵⁸ Council Decision 95/468/EC of 6 November 1995 on a Community contribution for telematic interchange of data between administrations in the Community (IDA), OJ L 269, 11.11.1995, p. 23

improvements to their E-mail communications with the Commission (and among their members) through the "E-mail for committees" project. These are a few examples of the actions funded through the different programmes.

3°/4°/5° Needs, Impediments, Next steps

The **user-needs** that flow from cooperation between national administrations and between them and the Commission should be the driving force and motivation for the TNA actions of the Community (Commission and the Member States). Such actions should be fully integrated into the policy of the administrations and in the Community legislation of the sectors concerned. These user-needs should determine where the operational networks are needed, what is the use provided by these networks and what is the quality of service required.

Numerous discussions have taken place with the Member States on how to tailor the Communities' TNA contribution in terms of scope, financing and management. The IDA Decision should be implemented and all the budget allocated to it released without further delay, in order to give the existing projects the support they require. Further projects should be introduced in accordance with the needs of administrations as mentioned above.

This programme provides essential support for cooperation in many of the areas mentioned in this report, and needs to be expanded to enable other sectors to benefit from modern communications between administrations. Without sufficient funding, there is a risk that even some of the projects already started will have to be abandoned.

23. The KAROLUS Exchange Programme

1° Introduction

The Karolus Programme was initiated in 1993, for five years⁵⁹. It provides for exchanges of officials between Member States' administrations in the internal market field. It enables participants to work with their counterparts in another Member State for some two months. The aim is to harmonize interpretation of Community legislation and implement it consistently.

2° Progress

Of 280 applications accepted by 14 November 1995, 193 had led to exchanges being carried out by the same date, together with introduction and assessment seminars. Participants said that the exchanges had led to a better understanding among officials from the different Member States working in the same area, a fruitful exchange of experience and the establishment of network of contacts which would allow effective and concrete cooperation.

Among the areas considered to be priority ones, public procurement, foodstuffs, product conformity assessment, market supervision and pharmaceutical products accounted for most exchanges. All 12 Member States (1993-1994) participated in that they both sent and received participants. Most of those taking part came from national administrations, with local ones nonetheless being well represented, more especially in the case of Spain (autonomous communities) and Germany (Länder). The leading host countries are France and the United Kingdom, while the main ones of origin are Italy, Spain, the United Kingdom, Germany and Greece. The new Member States are beginning to take an active part.

3° Results so far

The number of participants is much lower than was expected, at no more than one third or so of the Programme's potential. There are several reasons for this: language difficulties, 50% contribution by the Member State of origin to subsistence expenses, lack of encouragement from administrations and difficulties experienced in taking two months off.

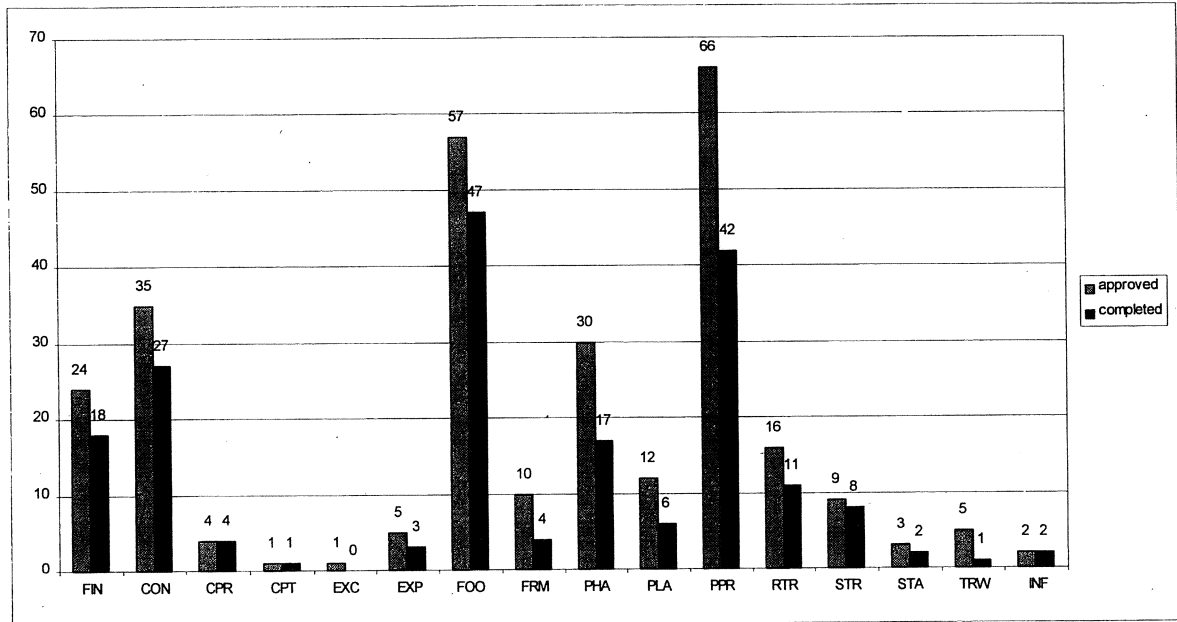
It is now for the Commission to assess the Karolus Programme, by the end of March 1996. The assessment will look at the Programme's operation and its contribution to the process of administrative cooperation between Member State administrations and its results. It will serve as a basis for thinking about the future development of the Programme.

4° Next steps

Depending on the results of this assessment, amendments to the Council Decision might be proposed, such as including seminars and short visits in the Programme. However, two-month exchanges have proved their value and there should be a campaign to make potential candidates more aware of them, in close collaboration with the Member States.

⁵⁹ Council Decision 92/481/EEC of 22 September 1992, OJ L 286, 1.10.1992, p. 65

Table 2: *Karolus exchanges ranked by priority area*
(period 1.1.93 - 14.11.95, total 280 approved, 193 completed)



Key

- FIN Banking, insurance, stock exchanges
- CON Conformity testing and market supervision
- CPR Consumer protection
- CPT Competition
- EXC Export controls on cultural goods
- EXP Export controls on certain dual-use goods and technologies
- FOO Foodstuffs
- FRM Free movement of persons
- PHA Pharmaceutical products
- PLA Animal and plant health controls
- PPR Public procurement
- RTR Road Transport
- STR Sea transport
- STA Statistical programmes
- TRW Transfer of waste
- INF Directive 83/189/EEC - exchange of information