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Information and Notices

(1) Text with EEA relevance

(Continued overleaf)

EN

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(Information)

COMMISSION

Ecu (1)

17 March 1997

(97/C 87/01)

Currency amount for one unit:

Belgian and Luxembourg franc	40,1466	Finnish markka	5,84055
Danish krone	7,43511	Swedish krona	8,93309
German mark	1,94601	Pound sterling	0,724432
Greek drachma	307,316	United States dollar	1,15380
Spanish peseta	165,363	Canadian dollar	1,57771
French franc	6,56745	Japanese yen	142,518
Irish pound	0,741519	Swiss franc	1,67682
Italian lira	1951,40	Norwegian krone	7,90298
Dutch guilder	2,18980	Icelandic krona	82,0239
Austrian schilling	13,6956	Australian dollar	1,45407
Portuguese escudo	195,893	New Zealand dollar	1,66087
		South African rand	5,11885

The Commission has installed a telex with an automatic answering device which gives the conversion rates in a number of currencies. This service is available every day from 3.30 p.m. until 1 p.m. the following day.

Users of the service should do as follows:

— call telex number Brussels 23789,

— give their own telex code,

— type the code 'cccc' which puts the automatic system into operation resulting in the transmission of the conversion rates of the ecu,

— the transmission should not be interrupted until the end of the message, which is marked by the code 'ffff'.

Note: The Commission also has an automatic fax answering service (No 296 10 97/296 60 11) providing daily data concerning calculation of the conversion rates applicable for the purposes of the common agricultural policy.

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(1) Council Regulation (EEC) No 3180/78 of 18 December 1978 (OJ No L 379, 30. 12. 1978, p. 1), as last amended by Regulation (EEC) No 1971/89 (OJ No L 189, 4. 7. 1989, p. 1).

Council Decision 80/1184/EEC of 18 December 1980 (Convention of Lomé) (OJ No L 349, 23. 12. 1980, p. 34).

Commission Decision No 3334/80/ECSC of 19 December 1980 (OJ No L 349, 23. 12. 1980, p. 27).

Financial Regulation of 16 December 1980 concerning the general budget of the European Communities (OJ No L 345, 20. 12. 1980, p. 23).

Council Regulation (EEC) No 3308/80 of 16 December 1980 (OJ No L 345, 20. 12. 1980, p. 1).

Decision of the Council of Governors of the European Investment Bank of 13 May 1981 (OJ No L 311, 30. 10. 1981, p. 1).

LIST OF DOCUMENTS FORWARDED BY THE COMMISSION TO THE COUNCIL DURING THE PERIOD 3 TO 7. 3. 1997

(97/C 87/02)

These documents may be obtained from the Sales Offices, the addresses of which are given on the back cover

Code	Catalogue No	Title	Date adopted by the Commission	Date forwarded to the Council	Number of pages
COM(97) 18	CB-CO-97-013-EN-C	Proposal for a Council Regulation (EC) apportioning the quantities of grain provided for under the Food Aid Convention 1995 (2)	3. 3. 1997	4. 3. 1997	8
COM(97) 78	CB-CO-97-071-EN-C	Proposal for a Council Decision concerning the conclusion of the Cooperation Agreement between the European Community and the Kingdom of Cambodia (2)	3. 3. 1997	4. 3. 1997	35
COM(97) 79	CB-CO-97-072-EN-C	Proposal for a Council Decision concerning the conclusion of the Cooperation Agreement between the European Community and the Lao People's Democratic Republic (2)	3. 3. 1997	4. 3. 1997	33
COM(97) 82	CB-CO-97-074-EN-C	Proposal for a Council Regulation (EC) opening and providing for the administration of Community tariff quotas and ceilings and establishing Community surveillance for certain fish and fishery products origination in the Faroe Islands and defining detailed provisions for amending and adapting these measures	3. 3. 1997	4. 3. 1997	16
COM(97) 83	CB-CO-97-075-EN-C	Proposal for a Council Regulation (EC) amending Regulation (EEC) No 1765/92 establishing a support system for producers of certain arable crops (2)	3. 3. 1997	4. 3. 1997	6
COM(97) 85	CB-CO-97-077-EN-C	Commission memorandum on acquired rights of workers in cases of transfers of undertakings (3)	4. 3. 1997	4. 3. 1997	21
COM(97) 90	CB-CO-97-078-EN-C	Proposal for a Council Regulation concerning amending Regulation (EEC) No 1789/81 laying down general rules concerning the system of minimum stocks in the sugar sector	3. 3. 1997	4. 3. 1997	5
COM(97) 100	CB-CO-97-084-EN-C	Commission opinion pursuant to Article 189b (2) (d) of the EC Treaty, on the European Parliament's amendments to the Council's common position regarding the proposal for a European Parliament and Council Directive on a common framework for general authorizations and individual licences in the field of telecommunications services (3)	3. 3. 1997	4. 3. 1997	10
COM(97) 76	CB-CO-97-068-EN-C	Amended proposal for a Council recommendation on a parking card for people with disabilities (2) (3)	4. 3. 1997	5. 3. 1997	12

Code	Catalogue No	Title	Date adopted by the Commission	Date forwarded to the Council	Number of pages
COM(97) 101	CB-CO-97-085-EN-C	Commission opinion pursuant to Article 189b (2) (d) of the EC Treaty, on the European Parliament's amendments to the Council's common position regarding the proposal for a European Parliament and Council Decision on a coordinated authorization approach in the field of satellite personal-communication services in the Community (3)	5. 3. 1997	5. 3. 1997	6
COM(97) 94	CB-CO-97-080-EN-C	Commission opinion pursuant to Article 189b (2) (d) of the EC Treaty, on the European Parliament's amendments to the Council's common position regarding the proposal for a European Parliament and Council Directive concerning the processing of personal data and the protection of privacy in the telecommunications sector, in particular in the integrated services digital network (ISDN) and in the public digital mobile networks (3)	5. 3. 1997	6. 3. 1997	11
COM(97) 95	CB-CO-97-081-EN-C	Proposal for a Council Regulation (EC) opening and providing for the management of autonomous Community tariff quotas for certain live fish originating in the Czech Republic and Slovakia	6. 3. 1997	6. 3. 1997	8
COM(97) 12	CB-CO-97-008-EN-C	Proposal for a Council Decision concerning the Community position within the Association Council on the participation of Hungary in Community programmes in the fields of training, youth and education (2)	5. 3. 1997	7. 3. 1997	22
COM(97) 13	CB-CO-97-009-EN-C	Proposal for a Council Decision concerning the Community position within the Association Council on the participation of the Czech Republic in Community programmes in the fields of training, youth and education (2)	5. 3. 1997	7. 3. 1997	23
COM(97) 14	CB-CO-97-010-EN-C	Proposal for a Council Decision concerning the Community position within the Association Council on the participation of Romania in Community programmes in the fields of training, youth and education (2)	5. 3. 1997	7. 3. 1997	22
COM(97) 81	CB-CO-97-093-EN-C	Proposal for a Council Decision concerning the conclusion of the Agreement in the form of an Exchange of Letters adding to the Free Trade Agreement the European Economic Community and the Swiss Confederation an additional Protocol on mutual administrative assistance in customs matters	5. 3. 1997	7. 3. 1997	19

Code	Catalogue No	Title	Date adopted by the Commission	Date forwarded to the Council	Number of pages
COM(97) 103	CB-CO-97-096-EN-C	Amended proposal for a European Parliament and Council Regulation (EC) establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products (2)	7. 3. 1997	7. 3. 1997	25

(1) This document contains an impact assessment on business, and in particular on SMEs.

(2) This document will be published in the *Official Journal of the European Communities.*

(3) Text with EEA relevance.

NB: COM documents are available by subscription, either for all editions or for specific subject areas, and by single copy, in which case the price is based pro rata on the number of pages.

Notice of the expiry of certain anti-dumping measures

(97/C 87/03)

The Commission gives notice that the anti-dumping measures mentioned below will shortly expire.

This notice is published in accordance with Article 11 (2) of Council Regulation (EC) No 384/96 of 22 December 1995 on protection against dumped imports from countries not members of the European Community (1).

Product	Country(ies) of origin or exportation	Measure	Reference	Date of expiry
Certain thermal paper	Japan	Duty	Regulation (EEC) No 729/92	28. 3. 1997
		Undertaking	Decision 92/177/EEC (OJ No L 81, 26. 3. 1992)	

(1) OJ No L 56, 6. 3. 1996, p. 1.

Notice of the expiry of certain anti-dumping measures

(97/C 87/04)

The Commission gives notice that the anti-dumping measures mentioned below will shortly expire.

This notice is published in accordance with Article 11 (2) of Council Regulation (EC) No 384/96 of 22 December 1995 on protection against dumped imports from countries not members of the European Community [1].

Product	Country(ies) of origin or exportation	Measure	Reference	Date of expiry
Cotton yarn	Brazil Turkey	Duty	Regulation (EEC) No 738/92 (OJ No L 82, 27. 3. 1992)	28. 3. 1997

[1] OJ No L 56, 6. 3. 1996, p. 1.

COMMUNICATION FROM THE COMMISSION UNDER ARTICLE 4 (1) (a) OF COUNCIL REGULATION (EEC) No 2408/92

Imposition of public service obligations in respect of seasonal scheduled through air services between Paris-Orly and Rochefort-Saint-Agnan

(97/C 87/05)

(Text with EEA relevance)

I. Pursuant to Article 4 (1) (a) of Council Regulation (EEC) No 2408/92 of 23 July 1992 on access for Community air carriers to intra-Community air routes, France has decided to impose public service obligations in respect of scheduled seasonal air services operated between Paris-Orly and Rochefort-Saint-Agnan as from 31 May 1997.

II. Public service obligations:

— *Type of aircraft used and capacity provided:*

The services must be operated using a turboprop aircraft with a minimum capacity of 46 seats.

— *Minimum frequency:*

The services must be operated for at least 10 weeks, from the last Friday in June to the first Monday in September, at the rate of at least one return trip per week, on Fridays in the direction Paris-Rochefort and on Mondays in the direction Rochefort-Paris.

The services must be operated without a stopover between Paris-Orly and Rochefort-Saint-Agnan.

— *Timetables:*

The proposed timetables must be as close as possible to the following:

— Departure Paris: 20h30 (Fridays)

— Arrival Paris: 8h40 (Mondays)

— *Marketing of flights:*

Flights must be marketed using at least one computerized reservation system.

— *Fares:*

The price of a single ticket must not exceed FF 999,00, including tax, at 1997 values, as the standard fare.

The price of a return ticket must not exceed FF 1 499,00, including tax, at 1997 values, as the standard fare.

These maximum fares may be adjusted each year on the basis of changes in the retail price index over the 12 months.

This adjustment must be notified to the carriers operating the route by registered mail 90 days before it takes effect. The European Commission must at the same time be informed of the adjustment, which will be published in the *Official Journal of the European Communities.*

If an abnormal and unforeseeable increase in the cost factors affecting the operation of the route takes place for which the carriers are not responsible, the fares may be raised in proportion to the increase. The new maximum fares will be notified to the carriers operating the route and will apply within an appropriate period. They will also be notified forthwith to the European Commission for publication in the *Official Journal of the European Communities.*

— *Continuity of service:*

Except in cases of *force majeure*, the number of flights cancelled for reasons directly attributable to the carrier must not exceed 2 % of the number of flights scheduled in any IATA scheduling season. Furthermore, the carrier must give at least six months' notice before discontinuing services.

STATE AID

C 51/96 (ex NN 71/96)

Italy (Sardinia)

(97/C 87/06)

(Articles 92 to 94 of the Treaty establishing the European Community)

Commission communication pursuant to Article 93 (2) of the EC Treaty to the other Member States and interested parties regarding Italian aid (region of Sardinia) granted to the milk sector through subsidized short-term loans (crédits de gestion)

By the following letter, the Commission informed the Italian Government of its decision to initiate the procedure.

'Following a complaint, by letter dated 24 January 1996, the Commission requested the Italian Government to notify the aid measures covered by Decision No 47/17 of the Regional Executive of the Sardinia Region of 24 October 1995 (hereinafter referred to as "Decision No 47/17".

By letter dated 1 March 1996, the Italian Permanent Representative to the European Union notified the measures in question.

Decision No 47/17 of 24 October 1995 lays down rules for applying Article 16 of Regional Law No 9 of 13 July 1962 (hereinafter referred to as "Regional Law No 9/62") for 1995/96. That Law has never been notified under Article 93 (3) of the Treaty. The compatibility of the aid provided for therein with the common market has never therefore been examined.

The Commission has decided to open the procedure provided for in Article 93 (2) of the Treaty with regard to this aid in the form of short-term low-interest loans granted pursuant to Article 9 of Regional Law No 9/62.

The aid

Processing of sheep's and goat's milk

Article 16 of Regional Law No 9/62 provides for the granting of aid in the form of reduced interest rates on short-term loans for the operation of milk-processing undertakings. Article 16 provides for a maximum rate of interest of 2 % to be paid by recipients and a regional guarantee on loans of up to 80 % of the amount due.

Decision No 47/17 lays down the rules for granting the aid provided for in abovementioned Article 16 for the 1995/96 agricultural year. No information has been supplied on the rules of application adopted for previous years.

The types of loan concerned are:

(a) operating loans (for cooperatives only):

these loans amount to Lit 250 per litre of milk with a ceiling fixed on the basis of production in the previous year;

(b) loans to cover advance payments to members (of cooperatives and producers' associations).

These loans amount to Lit 1 150 per litre of sheep's milk and Lit 850 per litre of goat's milk.

The duration of loans can be set by the financial institute at 18 or 36 months (according *inter alia* to the type of cheese produced).

The interest rate on the loans is 55 % of the reference rate fixed by the Government.

The above aid may be received in combination, in the case of cooperatives, with aid in the form of a refund of 10 % of the reduced rate of interest where cooperatives implement a joint marketing strategy (for example, by forming a marketing consortium or by means of worker participation agreements) for more than 30 000 quintals of product per year.

The Commission's arguments

Articles 92 and 93 of the Treaty apply to milk and milk products in accordance with Article 23 of Regulation (EEC) No 804/68 on the common organization of the market in the sector.

The abovementioned aid measures must be examined in the light of the criteria laid down in the Commission Communication on State aids: subsidized short-term loans in agriculture (*crédits de gestion*) [1]. In principle, those criteria apply to all aid measures applicable on or after 1 January 1996 (Commission letter to the Member States dated 20 October 1995).

The legal basis from the aid is Article 16 of Regional Law No 9/62. Since that Law has never been notified to or examined by the Commission under Articles 92 and 93 of the Treaty, the aid cannot be considered existing aid within the meaning of Article 93 (1).

As regards existing aid, i.e. aid notified to and approved by the Commission on the basis of its policy on *crédits de gestion* in force before the adoption of the abovementioned framework, by the Decision of 27 June 1966, the Commission extended the deadline for Member States to comply with the new rules to 31 December 1996. That extension therefore only applies to aid which the Commission declared compatible with the common market because it fulfilled the two negative criteria it applied before adopting the new rules (subsidized loans must not be for more than one year and must not be granted for a single product and a single operation). That extension is clearly not applicable in the case in point since Article 93 (3) of the Treaty was not complied with and no information has been supplied to show that the criteria applicable to aid of this type before the new rules were adopted were fulfilled.

Under the new rules, the aid measures in question must *inter alia* fulfil the following conditions:

(i) they must not be used selectively to assist sectors or individual agricultural operators for reasons which are not exclusively connected with the agricultural sector as a whole and related activities (in particular, the seasonal nature of agricultural production and holding structures); the Commission does not authorize aid which is not granted to all operators in the sector in the administrative unit concerned on a non-discriminatory basis irrespective of the agricultural activity (or activities) for which the operator needs short-term loans;

(ii) the aid must not exceed the difference between the interest rate paid by a typical operator in the agricultural sector concerned and the interest paid in

[1] OJ No C 44, 16. 2. 1996, p. 2.

the rest of the economy of the Member State for short-term loans of a similar amount per operator, not linked with investments;

(iii) the amounts of subsidized loans must not exceed cash-flow requirements arising from the fact that production costs are incurred before income from output sales is received; in no case may aid be linked to particular marketing or production operations;

(iv) subsidized short-term loans may be granted for a maximum of one year.

The aid in question does not comply with points (i) and (iv). No information showing compliance with points (ii) and (iii) has been provided.

Furthermore, the aid is granted on the quantity of milk sent for processing and therefore would appear to be in breach to Article 24 of Regulation (EEC) No 804/68 on the common organization of the market in milk and milk products, which forbids any aid the amount of which is calculated on the basis of the price or quantity of products covered by that market organization.

Under the procedure provided for in Article 93 (2) of the Treaty, the Commission hereby gives notice to the Italian Government to submit its comments within one month.

It also gives notice, by publishing a notice in the *Official Journal of the European Communities*, to the Governments of the other Member States and to other interested parties to submit their comments within the same time limit.

The Commission would draw the attention of the Italian Government to the letter it sent to all the Member States on 3 November 1983 concerning their obligations under Article 93 (3) of the EC Treaty and to the notice published in the *Official Journal of the European Communities* No C 318 of 24 November 1983, page 3, which states that any aid granted illegally, i.e. without a final decision under the procedure laid down in Article 93 (2) of the Treaty having been reached, is likely to be the subject of a request for reimbursement and/or a refusal to pay advances from the EAGGF or to charge to the EAGGF budget expenditure on national measures directly affecting Community measures.

Any reimbursement must be made in accordance with Italian law and will include interest calculated on the basis of the rate used as the reference rate in assessing regional aid schemes and running from the date on which the illegal aid was paid.'

The Commission gives notice to the other Member States and interested parties to submit their comments within one month of the date of this publication to:

European Commission
Rue de la Loi/Wetstraat 200,
B-1049 Brussels.

The comments will be sent to the Italian Government.

II

(Preparatory Acts)

COMMISSION

Amended proposal for a European Parliament and Council Directive amending the Directive proposal on *in vitro* diagnostic medical devices [1]

(97/C 87/07)

COM(96) 643 final — 95/0013(COD)

(Submitted by the Commission pursuant to Article 189a (2) of the EC Treaty on 20 December 1996)

[1] OJ No C 172, 7. 7. 1995, p. 21.

INITIAL TEXT	MODIFIED TEXT
Recital 3	
Whereas the harmonization of national legislations is the only means of removing these barriers to free trade and preventing new barriers; whereas this objective cannot be achieved in a satisfactory manner at another level by the individual Member States; whereas this Directive only lays down necessary and sufficient requirements for the free circulation of the *in vitro* diagnostic medical devices to which it is applicable;	Whereas the harmonization of national legislations is the only means of removing these barriers to free trade and preventing new barriers; whereas this objective cannot be achieved in a satisfactory manner at another level by the individual Member States; whereas this Directive only lays down necessary and sufficient requirements for the free circulation, in the best possible safety conditions, of the *in vitro* diagnostic medical devices to which it is applicable;
Recital 5	
Whereas *in vitro* diagnostic medical devices should provide patients, users and third parties with a high level of protection and attain the performance levels attributed to them by the manufacturer; whereas, therefore, the maintenance or improvement of the level of protection attained in the Member States is one of the essential objectives of this Directive;	Whereas *in vitro* diagnostic medical devices should provide patients, users and third parties with a high level of health protection and attain the performance levels originally attributed to them by the manufacturer; whereas, therefore, the maintenance or improvement of the level of health protection attained in the Member States is one of the essential objectives of this Directive;
Recital 6	
Whereas, in accordance with the principles set out in the Council resolution of 7 May 1985 concerning a new approach to technical harmonization and standardization, rules regarding the design and manufacture of relevant products must be confined to the provisions required to meet the essential requirements; whereas because they are essential, such requirements should replace the corresponding national provisions; whereas the essential requirements, including requirements to minimize and reduce risks, should be applied with	Whereas, in accordance with the principles set out in the Council resolution of 7 May 1985 concerning a new approach to technical harmonization and standardization, rules regarding the design, manufacture and packaging of relevant products must be confined to the provisions required to meet the essential requirements; whereas because they are essential, such requirements should replace the corresponding national provisions; whereas the essential requirements, including requirements to minimize and reduce risks, should be

INITIAL TEXT	MODIFIED TEXT
discretion, taking into account the technology an practice at the time of design and of technical and economic considerations compatible with a high level of protection of health and safety;	applied with discretion, taking into account the technology and practice at the time of design and of technical and economic considerations compatible with a high level of protection of health and safety;
	Recital 9a (new)
	Whereas mechanical laboratory equipment especially designed for *in vitro* diagnostic examinations falls within the scope of this Directive; whereas, therefore, in order to harmonize the relevant Directives, Directive 89/392/EEC (1) as last amended by Directive 93/68/EEC (2) should be appropriately amended to bring it into line with this Directive;
	Recital 15
Whereas the list of *in vitro* diagnostic medical devices to be subjected to third party conformity assessment needs updating, taking account of technological progress and of evolution in the domain of protection of health; whereas such updating measures must be taken in line with the procedure IIIa as laid down in Council Decision 87/373/EEC (1); whereas a system of adverse incident reporting (vigilance) constitutes a useful tool for the surveillance of the market, including the performance of new devices; whereas information obtained from vigilance as well as from external quality assessment schemes becomes useful for decision-making on classification of devices;	Whereas the list of *in vitro* diagnostic medical devices to be subjected to third party conformity assessment needs updating, taking account of technological progress and of evolution in the domain of protection of health; whereas such updating measures must be taken in line with the procedure IIIa as laid down in Council Decision 87/373/EEC (3); whereas an agreement on a *modus vivendi* between the European Parliament, the Council and the Commission concerning the implementation measures of the acts adopted pursuant to the procedure referred to in Article 189b of the EC Treaty took place on 20 December 1994; whereas a system of adverse incident reporting (vigilance) consitutes a useful tool for the surveillance of the market, including the performance of new devices placed on the market; whereas information obtained from vigilance as well as from external quality assessment schemes becomes useful for decision-making on classification of devices;
	Recital 18
Whereas the competent authorities in charge of market surveillance must be able, particularly in emergencies, to contact the manufacturer or his authorized representative established in the Community; whereas cooperation and exchange of information between Member States are necessary in view of uniform application of this Directive, in particular for the purpose of market surveillance;	Whereas the competent authorities in charge of market surveillance must be able, particularly in emergencies, to contact the manufacturer or his authorized representative established in the Community, in order to take any protection measures that should prove necessary; whereas cooperation and exchange of information between Member States are necessary in view of uniform application of this Directive, in particular for the purpose of market surveillance;

(1) OJ No L 197, 18. 7. 1987, p. 33.

(1) OJ No L 183, 29. 6. 1989, p. 9.
(2) OJ No L 220, 30. 8. 1993, p. 1.
(3) OJ No L 197, 18. 7. 1987, p. 33.

INITIAL TEXT	MODIFIED TEXT
Article 1 (1)	
1. This Directive shall apply to *in vitro* diagnostic medical devices and their accessories. For the purposes of this Directive, accessories shall be treated as *in vitro* diagnostic medical devices in their own right. Both *in vitro* diagnostic medical devices and accessories shall hereinafter be termed devices.	1. This Directive shall apply to *in vitro* diagnostic medical devices, including therapy monitoring devices for diagnostic purposes, and their accessories. For the purposes of this Directive, accessories shall be treated as *in vitro* diagnostic medical devices in their own right. Both *in vitro* diagnostic medical devices, including therapy monitoring devices for diagnostic purposes, and accessories shall hereinafter be termed devices.
Article 1 (2) (b), first subparagraph	
(b) '*in vitro diagnostic medical device*' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information concerning a physiological state, state of health or disease or congenital abnormality or to determine the safety and compatibility with potential recipients. For the purpose of this Directive, a specimen receptacle, whether evacuated or not, specifically intended by its manufacturer to contain a specimen for the purpose of *in vitro* diagnostic examinations is considered to be a device.	(b) '*in vitro diagnostic medical device*' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information concerning a physiological state, pathological state or congenital abnormality or to determine the safety and compatibility with potential recipients. For the purpose of this Directive, a specimen receptacle, whether a vacuum-type or not, specifically intended by its manufacturer to contain a specimen for the purpose of *in vitro* diagnostic examination is considered to be a device.
Article 1 (2) (e)	
(e) '*Device for performance evaluation*' means any device intended by the manufacturer to be subject to one or more performance evaluation studies in clinical laboratories or in other appropriate environments outside his own premises;	(e) '*Device for performance evaluation*' means any device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analysis or in other appropriate environments outside his own premises;
Article 2	
Member States shall take all necessary steps to ensure that devices may be placed on the market and put into service only if they comply with the requirements laid down in this Directive when properly installed, maintained and used in accordance with their intended purpose.	1. Member States shall take all necessary steps to ensure that devices may be placed on the market and put into service only if they comply with the requirements laid down in this Directive when properly supplied, installed, maintained and used in accordance with their intended purpose.

INITIAL TEXT	MODIFIED TEXT
	2. Member States shall continuously monitor the safety and quality of devices placed on the market.
Article 3a (new)	
	This Directive shall not affect national laws which provide for the supply of diagnostic medical devices by a medical prescription.
Article 4 (2)	
2. At trade fairs, exhibitions, demonstrations, Member States shall not create any obstacle to the showing of devices which do not conform to this Directive, provided that a visible sign clearly indicates that such devices cannot be marketed or put into service until they have been made to comply.	2. At trade fairs, exhibitions, demonstrations or scientific and technical meetings, Member States shall not create any obstacle to the showing of devices which do not conform to this Directive, provided that a visible sign clearly indicates that such devices cannot be marketed or put into service until they have been made to comply.
Article 10, Title	
Registration of manufacturers	**Registration of manufacturers and devices**
Article 11 (3)	
3. After carrying out an assessment, if possible together with the manufacturer, Member States shall, without prejudice to Article 8, immediately inform the Commission and the other Member States of the incidents referred to in paragraph 1 for which relevant measures have been taken or are contemplated.	3. After carrying out an assessment, if possible together with the manufacturer, Member States shall, without prejudice to Article 8, immediately inform the Commission and the other Member States of the incidents referred to in paragraph 1 for which relevant measures, including possible withdrawal, have been taken or are contemplated.
Article 11 (4), Introduction	
4. Where, in the context of notification referred to in Article 10, a device notified, bearing a CE marking, is a 'new' product, the manufacturer shall indicate this fact on his notification. The competent authority so notified may at any time within the following two years and on justified grounds, require the manufacturer to submit a report relating to the experience with the device subsequent to its being placed on the market. For this purpose, a device is 'new' if:	4. Where, in the context of notification referred to in Article 10, a device notified, bearing a CE marking, is a 'new' product, the manufacturer shall indicate this fact on his notification. The competent authority so notified may at any time within the following two years and on justified grounds, require the manufacturer to submit a report relating to the experience gained with the device subsequent to its being placed on the market. For this purpose, a device is 'new' if:

INITIAL TEXT	MODIFIED TEXT
Article 11 (5a) (new)	
	5a. In addition, the data provided by the manufacturers in accordance with Article 10 shall be stored in a Community database accessible to the competent authorities to enable them to conduct vigilance on a well-informed basis. Such data is to be forwarded in a standardized format.
Article 13 (2)	
2. Member States shall apply the criteria set out in Annex 9 for the designation of bodies. Bodies that meet the criteria laid down in the national standards which transpose the relevant harmonized standards shall be presumed to meet the relevant criteria.	2. Member States shall apply the criteria set out in Annex 9 for the designation of bodies. Bodies that meet the criteria laid down in the national standards which transpose the relevant harmonized standards shall be presumed to meet the criteria applicable in accordance with the said Annex 9.
Article 16 (2)	
2. In the event of a decision as referred to in paragraph 1, the manufacturer, or his authorized representative established in the Community, shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measure to be taken.	2. In the event of a decision as referred to in paragraph 1, the manufacturer, or his authorized representative established in the Community, shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measure to be taken, as justified by public health requirements.
Article 19 (1) (a)	
Article 1 (2) (c) (Directive 93/42/EEC)	
'(c) *in vitro* diagnostic medical device means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information concerning a physiological state, state of health or disease or congenital abnormality or to determine the safety and compatibility with potential recipients.'	'(c) *in vitro* diagnostic medical device means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information concerning a physiological state, pathological state or congenital abnormality or to determine the safety and compatibility with potential recipients.'

INITIAL TEXT	MODIFIED TEXT
Article 19 (1) (ab) (new)	
Article 1 (2) (ia) (new) (Directive 93/42/EEC)	
	(ab) In Article 1 (2), the following point (ia) shall be added:
	'(ia) authorized representative means the natural or legal person as established within the Community who, being explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community in substitution for the manufacturer with regard to the latter's obligations in accordance with this Directive.'
Article 19 (1) (b)	
Article 1 (5) (f) (Directive 93/42/EEC)	
'(f) transplants or tissues or cells of human origin, unless a device is manufactured utilizing tissues or substances derived from such tissues which are non viable or rendered non viable. In this case, the Directive shall not affect national regulations relating to the ethics of the collection of tissues or substances of human origin, as well as any regulations relating to the ethics governing distribution of given types of devices of such origin.'	'(f) transplants or tissues or cells of human origin, unless a medical device is manufactured utilizing cells or tissue of human origin having undergone a process of transformation which removes the cellular organization or the characteristic structure of the tissue of origin and renders such material non viable. In this case, the Directive shall not affect national regulations relating to the ethics of the collection of tissues or substances of human origin, as well as any regulations relating to the ethics governing distribution of given types of devices of such origin.'
Article 19 (1) (ba) (new)	
Article 2 (Directive 93/42/EEC)	
	(ba) Article 2 shall read as follows:
	'*Article 2*
	Member States shall take all necessary steps to ensure that devices may be placed on the market and put into service only if they comply with the requirements laid down in this Directive when properly supplied, installed, maintained and used in accordance with their intended purpose.'

INITIAL TEXT	MODIFIED TEXT
Article 19 (1) (c)	
Annex I (8) (2), first subparagraph (Directive 93/42/EEC)	
'8.2. Where a device is manufactured utilizing human tissues or substances derived from human tissues, the use of such tissues or substances must be subject to the relevant validated selection and screening procedures, including traceability as appropriate in relation to the inherent risk.'	'8.2. Where a medical device is manufactured utilizing human tissues or cells or substances derived from human tissues, as described in Article 1 (5) (f) above, the use thereof must be subject to the relevant validated selection and screening procedures, including traceability as appropriate in relation to the inherent risk.'
Article 19 (1) (d)	
Annex I (13) (3) (n) (Directive 93/42/EEC)	
'(n) in the case of devices incorporating tissues of human origin or substances derived from such tissues, a statement indicating that the device incorporates tissue or substances derived from tissue of human origin as appropriate.'	'(n) in the case of medical devices which, during manufacture, utilize cells or tissues of human origin or substances derived from such tissues, a statement indicating that the medical device contains substances of human origin;'
Article 19 (1) (e)	
Annex II (3) (2) (c) and Annex III (3), third last indent (Directive 93/42/EEC)	
'— in the case of devices incorporating tissues of human or animal origin, information on the selection and origin;'	'— in the case of medical devices manufactured using substances derived from cells or tissues of human or animal origin, information on the selection and origin;'
Article 19 (1) (f)	
Annex IX (III) (4) (5), last subparagraph (Directive 93/42/EEC)	
'All devices manufactured utilizing human tissues or substances derived from such tissues are in class III.'	'All medical devices which during their manufacture utilize cells or tissues of human origin or substances produced therefrom are in class III.'

INITIAL TEXT	MODIFIED TEXT
Annex 1 (1)	
1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise, directly or indirectly, the clinical condition or the safety of the patients, the safety and health of users and, where applicable, other persons, and the safety of property, Any risks, which may be associated with their use, must be acceptable when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	1. The devices must be designed, manufactured and packaged in such a way that, when used under the conditions and for the purposes intended, they will not compromise, directly or indirectly, the clinical condition or the safety of the patients, the safety and health of users and, where applicable, other persons, and the safety of property. Any risks, wich may be associated with their use, must be acceptable when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.
Annex 1 (2), second subparagraph, first indent	
— eliminate or reduce risks as far as possible (inherently safe design and construction),	— eliminate or reduce risks as far as possible (inherently safe design, construction, and packaging)
Annex 1 (6) (1) and (6) (2)	
6.1. The devices must be designed and manufactured in such a way as to achieve the characteristics and performances referred to in Section I, 'General Requirements'. Attention must be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the samples (such as biological tissues, cells, body fluids and micro-organisms) intended to be used with the device, taking account of its intended purpose.	6.1. The devices must be designed, manufactured and packaged in such a way as to achieve the characteristics and performances referred to in Section I, 'General Requirements'. Attention must be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the samples (such as biological tissues, cells, body fluids and micro-organisms) intended to be used with the device, taking account of its intended purpose.
6.2. The devices must be designed, manufactured and packed in such a way as to reduce as to reduce as far as possible the risk posed by leakage products, contaminants and residues to the persons involved in the transport, storage and use of the devices, taking account of the intended purpose of the products.	6.2. The devices must be designed, manufactured and packed in such a way as to reduce to the minimum the risk posed by product leakage, contaminants and residues to the persons involved in the transport, storage and use of the devices, taking account of the intended purpose of the products.
Annex 1 (7) (1)	
7.1. The devices must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or other persons. The design must allow easy handling and, where necessary, reduce as far as possible contamination of and leakage from the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen. The manufacturing processes must be appropriate for these purposes.	7.1. The devices must be designed in such a way as to eliminate or reduce to the minimum all risk of infection to the user or other persons. The design must allow easy handling and, where necessary, reduce as far as possible contamination of and leakage from the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen. The manufacturing processes must be appropriate for these purposes.

INITIAL TEXT	MODIFIED TEXT
Annex 1 (7) (2)	
7.2. Where a device incorporates biological substances, the risks of infection must be reduced as far as possible by selecting appropriate donors, appropriate substances and using appropriate inactivation, conservation, test and control procedures.	7.2. Where a device incorporates biological substances, all risk of infection to the user or other persons must be eliminated or reduced to the minimum by selecting appropriate donors, appropriate substances and using appropriate inactivation, conservation, test and control procedures.
Annex 1 (7) (5)	
7.5. Packaging systems for devices other than those referred to in section 7.3 must keep the product without deterioration at the level of cleanliness, if any, as indicated by the manufacturer and, if the devices are to be sterilized prior to use, reduce as far as possible the risk of microbial contamination.	7.5. Packaging systems for devices other than those referred to in section 7.3 must keep the product without deterioration at the level of cleanliness, if any, as indicated by the manufacturer and, if the devices are to be sterilized prior to use, reduce to the minimum the risk of microbial contamination.
Steps shall be taken to reduce microbial contamination during selection and handling of raw materials, manufacture, storage and distribution where the performance of the device can be adversely affected by such contamination.	Steps shall be taken to reduce as far as possible microbial contamination during selection and handling of raw materials, manufacture, storage and distribution where the performance of the device can be adversely affected by such contamination.
Annex 1 (8) (3) and (8) (4)	
8.3. Devices must be designed and manufactured in such a way as to reduce as far as possible the risks of fire or explosion during normal use. Particular attention must be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.	8.3. Devices must be designed, manufactured and packaged in such a way as to reduce as far as possible the risks of fire or explosion during normal use. Particular attention must be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.
8.4. Devices must be designed and manufactured in such a way as to facilitate the management of safe waste disposal.	8.4. Devices must be designed, manufactured and packaged in such a way as to facilitate the management of safe waste disposal.
Annex 1 (12), Introduction and (1)	
Devices for self-testing must be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can	Devices for self-testing must be designed, manufactured and packaged in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from

INITIAL TEXT	MODIFIED TEXT
reasonably be anticipated in users' technique and environment. The information and instructions provided by the manufacturer should be easily understood and applied by the user.	variation that can reasonably be anticipated in users' technique and environment. The information and instructions provided by the manufacturer should be easily understood and applied by the user.
12.1. Devices for self-testing must be designed and manufactured in such a way as to reduce as far as practicable the risk of user's error in handling and in interpretation of the result.	12.1. Devices for self-testing must de designed, manufactured and packaged in such a way as to reduce as far as practicable the risk of user's error in handling and in interpretation of the result.

Annex 2 (2)

2. Reagents and reagent products for the detection in human specimens of markers of HIV infection, Hepatitis B and C.	2. Reagents and reagent products for the detection in human specimens of markers of HIV infection, Hepatitis B and C, Rubella and toxoplasmosis.

Annex 7 (3) (2), third subparagraph (d)

(d) the appropriate test and trials to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible adequately to trace back the calibration of the test equipment.	(d) the appropriate tests and trials be carried out before, during and after manufacture, the frequency with which they will take place, and the equipment used; the calibration of this equipment must be such as to guarantee adequate traceability.

III

(Notices)

COMMISSION

Grotius — Annual programme and call for proposal for 1997

(97/C 87/08)

On 28 October 1996 the Council adopted the Grotius programme (1), a programme of incentives and exchanges for legal practitioners (joint action 96/636/JHA—OJ No L 287, 8. 11. 1996, p. 3). It applies to the Member States of the European Union.

The programme covers the period from 1996 to 2000 and the financial reference amount for implementing it comes to ECU 8 800 000.

1. In general, what the Grotius programme sets out to do is to support operations to foster mutual knowledge of the Member States' legal and judicial systems among legal practitioners, with a view to facilitating judicial cooperation. The first object is to awaken greater interest in the professional circles concerned, making practitioners, whatever their function or level of responsibility, aware of the need to become more familiar with each other's legal and judicial procedures, institutions and cultures and gradually persuading them of the benefits of incorporating the European dimension at every stage of their studies. Secondly, when practitioners facing the same conflicts or problems exchange experiences, it can be an opportunity for discovering that there are more similarities between them than differences, and that such differences as there are can be overcome if an atmosphere of openness, frankness and trust is established between them.

   To meet these aspirations, the following specific objectives are pursued:

   — to familiarize practitioners with institutions and procedures in the other Member States,

   — to establish professional contacts and contact structures,

   — to study and research the regulatory framework for legal cooperation,

   — to share thoughts on ways of enhancing legal cooperation,

   — to distribute information on ways of becoming familiar with the law in other Member States,

   — to bring knowledge of legal terminology up to comparable levels,

   — to exchange information on developments in Member States' law with a bearing on judicial cooperation,

   — to compare social and judicial trends and discuss reforms which are under way, and

   — to raise awareness of the incipient convergence of legal cultures in the European Union.

   Operations relating to training in Community law and the proper application thereof do not fall within the remit of the Grotius programme. On 19 November 1996 the Commission sent the Council a proposal for a decision establishing an action programme to improve awareness of Community law for the legal professions (Robert Schuman Project). The Council adopted in 1996 three other Title VI programmes: Sherlock (programme of training, exchanges and cooperation in the field of identity documents — OJ No L 287, 8. 11. 1996). Stop (incentive and exchange programme for persons responsible for combating trade in human beings and sexual exploitation of children — OJ No L 322, 12. 12. 1996) and Oisin (common programme for the exchange and training of, and cooperation between, law enforcement authorities — OJ No L 7, 10. 1. 1997). Combined financing under these different programmes is not allowed.

2. Expenditure directly chargeable to the implementation of such projects is eligible under the Grotius programme. The running costs of an organisation are not eligible, even where the organisation is pursuing the same goal as the Grotius programme. The grant from the Community may not exceed 80 % of the final cost of the project.

   Grants will be awarded in five areas:

   — language training and training in comparative law,

   — the organization of traineeships and visits abroad,

(1) This programme is sent to the European Parliament, that will decide, on this basis, on the transfer of the budget line allocated for 1997, currently in reserve.

— the holding of conferences,

— the coordination of research into subjects with a bearing on legal cooperation,

— the distribution of information about foreign law and legal cooperation.

3. The programme is directed at judges (including examining magistrates), prosecutors, advocates, solicitors, academic and scientific personnel, ministry officials, criminal investigation officers, court officers, bailiffs, court interpreters and all other professionals associated with the judiciary. The programme is not intended for students pursuing their initial studies but is open to young professionals undergoing training.

Project leaders may be local, national, european or international institutions, whether public or non-governmental, e.g. establishments which provide legal training and training for lawyers, research centres and professional associations. Initiatives by private individuals are not eligible for the programme.

Projects may associate practitioners from the States which have applied for membership where this would contribute to their preparation for accession, and practitioners from other non-Union countries, e.g. EEA countries, depending on the type and subject of the project concerned, if a contribution from them would help to achieve its purposes.

4. The criteria on which projects are selected for financing are as follows:

— the operational purpose, i.e. the extend to which stress is placed on passing on knowledge of immediate use in carrying on the professional activity concerned, without overlooking the need for thorough consideration of the cultural and sociological obstacles to cooperation,

— the number of practitioners likely to derive some advantage from the project, either directly or through contact between those who have taken part and those who have not had the opportunity,

— the accessibility of the project, i.e. the extent to which opportunity to participate is effectively open to all who may benefit, the approach taken, and the allowance which the organizational arrangements make for participants' existing knowledge and for professional constraints,

— the degree of preparation and the standard of organization, as well as clarity and precision as regards the objectives, design and planning of the project,

— partnership in the organizing of the project, openness to practitioners from different countries and disciplines and the opportunity for them to benefit from each other's experience,

— the extent to which the projects complement each other, the way in which they contribute to creating a forward momentum rather than merely juxtaposing isolated operations,

— the relevance of the project, for instance because it focuses closely on an issue that has so far received little discussion or because it is especially topical, for example in being linked to the implementation of legal cooperation instruments adopted by the Council.

5. The following guidelines, based on the above criteria, should be of assistance to applicants:

— ambitious schemes, schemes of long duration or those for which a large grant is being applied for should be preceded by pilot projects or feasibility studies,

— any plan for setting up a documentation network, data bases etc. should state in detail the sources, the field of investigation, the methodological approach, the frequency of updates etc.,

— research projects should not be limited to study based purely on the legal literature but should be based on practical experience and lead to usable conclusions,

— the knock-on effect of a project will be assessed from the point of view of the participants themselves as relays for the project, and/or from the point of view of how effectively the results of the project are disseminated. Projects likely to benefit only the applicant organization will not be considered,

— the standard of preparation will be assessed both objectively, as regards project design and planning, and subjectively, as regards the experience, reputation and means of the applicant organization. Initiatives submitted by organizations or associations having neither important structures nor significant human and financial ressources will not be disregarded. Previous records will be paid attention if a series of applications is received from the same organization,

— added value conferred by the involvement of several disciplines will be evaluated in terms of quality, not quantity, and will be assessed in terms of how the contributions from the various professional categories involved in a single project complement each other,

— active involvement of the participants will be regarded as a positive feature of a project,

— projects put forward as complementary may be supported as a group, or it may be suggested that independent projects be coordinated and rationalized.

6. Projects to be financed from the 1997 budget may relate to all the types of measure listed in point 2 and detailed in Articles 3, 4, 5, 6 and 7 of the Grotius programme, may be directed at all the professional categories referred to in point 3 and may concern any topic relating to judicial cooperation, whether civil or criminal, including if applicable aspects relating to prevention.

As a matter of principle, projects should concentrate on situations where practitioners and citizens experience practical difficulties. They should focus first on correct implementation of existing law, and explore available means of ensuring this implementation, before addressing the issue, if necessary, of possible legislative or conventional amendments. Special attention should be devoted to the reciprocal understanding of 'judicial thinking' in order to foster mutual confidence in cases requiring judicial cooperation.

Against this background, the following topics are suggested as being of particular interest:

Criminal law:

— action against drug trafficking (implementation of the resolution of 20 December 1996 on convictions for serious offences),

— action to combat racism and xenophobia (implementation of joint action 96/443/JHA of 15 July 1996),

— fight against organized crime,

— fight against economic crime,

— fight against fraud relating to Community financial interests,

— action against money laundering, notably seizure and confiscation,

— implementation of applicable judicial cooperation instruments, including regional and bilateral instruments to the extent that the project contributes to the furthering of cooperation within the European Union,

— special means of cooperation, such as:

  — protection for witnesses and informers (implementation of resolution 95/C 327/04 of 23 November 1995 and the resolution of 20 December 1996),

  — instruments for cross-border investigation.

Civil law:

— determination of competent judicial authority and enforcement of foreign judgments, particularly the application of the Brussels and Lugano Conventions,

— improving procedures for determining which laws apply to contractual obligations (the Rome Convention) and non-contractual obligations,

— other aspects of judicial cooperation, e.g. simplifying procedures for obtaining evidence from other Member States of the European Union, granting legal aid, etc.,

— cooperation between the judicial authorities and the competent administrative services of the Member States in particular fields (e.g. family law, labour law, social security law, consumer law, competition law, company law, bankruptcy etc.),

— protection of children's rights, particularly the application of the Strasbourg Conventions of 1980, 1993 and 1995,

In general:

— assistance with procedures (legal aid, protection for witnesses and informers, assistance for victims),

— protection of human dignity and privacy in audio-visual and electronic data transmissions,

— the learning of legal language in other Member States,

— training in comparative law,

— activities of liaison and contact magistrates.

As far as the types of project are concerned, preference will be given to training projects (within the meaning of Article 3 of the programme), exchange projects (Article 4) and projects for the distribution of information (Article 7), so as to balance the programme in comparison with more traditional activities such as meetings or research. Applications will be encouraged from organizations in EU Member States less well represented in the projects as a whole. Special attention will be given to projects open to professionals which have had less opportunities so far to get familiarized with other judicial cultures, and to projects open to practitioners from applicant countries. This approach will be used for selecting projects as well as for evaluating the financing granted.

7. Under the 1997 budget, which comes to ECU 2 000 000 in all, applications for grants must be submitted by 31 March 1997, to the Justice and Home Affairs Task Force (attention: Mr Wennerström, N-9 5/21), 200 rue de la Loi, B-1049 Brussels, using the application form in one of the 11 European Union languages (a translation may be

added in a second working language). Forms may be obtained by applying to the address above (tel. (32-2) 229 41 22/296 93 01, fax (32-2) 296 59 97). The purpose of the project must be described as briefly and accurately as possible in point 9 of the form, which is in fact the only document passed on to the members of the Committee referred to in Article 12 of the programme decision. These requests must deal with projects whose implementation should begin before the end of the current budget year and finish during the year following the decision to commit the funds. No financing will be provided in respect of expenditure incurred before the decision is taken to commit the funds.

A detailed estimated budget in national currency must be sent in with the application. An indication of the value in ecus may be attached. The budget must show the expected overall cost of the project. The grant applied for may not exceed 80 % of that cost. It may be reduced, in which case the applicant will be asked to state whether he undertakes to carry out the project at a lower level of financing.

Beneficiaries are required to state in all advertising or published material that their projects are in receipt of financial support from the Grotius programme. Within three months of the completion of their project, they must submit a report on the execution of the project, any obstacles encountered, the assessment given by the participants, the results obtained, the dissemination of such results and the conclusions drawn.

Oisin — Annual programme for 1997

(97/C 87/09)

On 20 December 1996 the Council adopted the Oisin programme [1], a framework to develop and enhance cooperation between police, customs and other law enforcement authorities [2] of Member States and to provide such authorities with a greater insight into the working methods of their counterparts in other Member States.

This programme has been established for an initial period: 1997 to 2000. The financial reference amount for implementing it for the period 1997 to 1999 is ECU 8 000 000.

The aim of the present document is twofold. It intends both to set out the priorities for the implementation of the programme in 1997 [3] as well as to provide general and practical information aimed at assisting applicants for grants in the formulation of projects.

1. In general, what the Oisin programme sets out to do is to stimulate and enhance dynamic webs of relations among law enforcement authorities throughout the European Union by providing a framework for the exchange and training of, and cooperation between the law enforcement authorities. This with a view to enhancing practical cooperation between law enforcement authorities and to contributing to an increase in the mutual knowledge and understanding of the legal systems and law enforcement practices of the Member States and to raise the level of expertise of law enforcement personnel of the Member States.

To meet these aspirations, the following specific objectives are pursued:

— to raise operational language skills and comprehension of other Member States' legal and operational terminology in order to develop quicker and more efficient communication between law enforcement authorities in the Union,

— to promote awareness of the legislation and operational procedures of other Member States, by means of training and exchange programmes,

— to establish networks of law enforcement authorities to further practical cooperation,

— to encourage exchange of experience among those responsible for the training of law enforcement authorities and the joint development of training material,

— to deepen research into matters of common interest to law enforcement authorities and the enhancement of existing techniques and the development of revised methods as a result of such research,

— to organize joint operational projects of limited duration in areas where such projects enhance cooperation between law enforcement authorities of more than one Member State,

— to promote continuous exchange of information on trends in matters of common interest in this area.

2. In 1996 the Council adopted three other programmes under Title VI of the Treaty: Sherlock (programme of training, exchanges and cooperation in the field of identity documents (OJ No L 287, 8. 11. 1996)), Grotius (programme of incentives and exchanges for legal practitioners (OJ No L 287, 8. 11. 1996)) and

[1] Joint Action 97/12/JHA, No L 7, 10. 1. 1997, p. 5.

[2] For the purpose of this programme, 'law enforcement authorities' means all public bodies existing in Member States which are responsible under national law for preventing, detecting and combating criminal offences.

[3] This programme is sent to the European Parliament who on the basis of which, will decide on the transfer of the amount foreseen for the year 1997, currently entered in Chapter B0-40.

Stop (incentive and exchange programme for persons responsible for combating trade in human beings and sexual exploitation of children (OJ No L 322, 12. 12. 1996)).

No funding will be provided under the Oisin programme where an alternative programme already exists which can comprehend more specifically or more appropriately the individual action proposed.

Grants will be awarded in four areas:

— provision of training,

— exchange of personnel and provision of operational expertise,

— research, operational studies and evaluation and operational projects,

— information exchange.

3. The programme is directed at law enforcement authorities and public bodies existing in the Member States of the European Union which are responsible under national law for preventing, detecting and combating criminal offences. This includes, *inter alia*, police, customs and other law enforcement authorities, training, research, and forensic personnel, and other bodies working in the areas of common interest as identified within the meaning of Article K1 (8) and K1 (9) of the Treaty on European Union.

Project leaders may be public or private institutions (e.g. establishments or associations which provide both basic and continuing training as well as those providing for research).

Applications for funding by natural individuals are not eligible for the programme.

The projects may involve those responsible in applicant countries in the framework of their preparation for accession, or in other third countries where it serves the aims of the projects.

4. The criteria on which projects are selected for financing are as follows:

— the European dimension of the project and the involvement of more than one Member State of the European Union,

— the consistency of the topics to be covered with the work undertaken in Council action programmes coming under police and customs cooperation,

— the operational purpose and practical input, i.e. the extent to which stress is placed in passing on knowledge of use in carrying on the professional activity concerned, without overlooking the need for a thorough consideration of the obstacles to cooperation,

— the number and the degree of preparation of law enforcement officers likely to derive some advantage from the project either directly or through contact between those who participated and those who have not,

— the degree of preparation and the standing of the institution responsible, as well as clarity and precision as regards the objectives, design and planning of the project,

— partnership in the organization of the project, openness to law enforcement personnel from different countries and different fields,

— the complementarity of the projects, i.e. the extent to which the projects contribute to creating a forward momentum rather than merely juxtaposing isolated operations.

5. The following guidelines, based on the above criteria, should be of assistance to applicants:

— ambitious schemes, schemes of long duration or those for which a large grant is being applied for should be preceded by pilot projects or feasibility studies,

— any plan for setting up a documentation network, databases, etc., should state in detail the sources, the field of investigation, the methodological approach, the frequency of updates, etc.,

— projects likely to benefit only the applicant organization will not be considered,

— the standard of preparation will be assessed both as regards projet designing and planning, and as regards the experience of the applicant organization. Previous records will be taken into consideration if a series of applications is received from the same organization,

— added-value conferred by the involvement of several disciplines will be evaluated in terms of how the contributions from the various professional categories involved in a single project complement each other,

— projects put forward as complementary may be supported as a whole, or it may be suggested to applicants that independent projects be coordinated and rationalized.

6. Projects to be financed from the 1997 budget may relate to all the types of measures mentioned in Section 2 and further detailed in Articles 3, 4, 5, 6 and 7 of the Joint Action establishing the Oisin programme and may be directed at all the entities referred to at Section 3 above.

Against this background, the following types of action are suggested as being of particular interest and priority for 1997:

— participation in strategic and pilot project operations, including joint surveillance operations as well as those in conjunction with specific international organizations,

— development of teaching frameworks and modules aiming to develop common approaches by Member States to training of law enforcement personnel,

— development of limited duration schemes for the exchange of law enforcement officials,

— organization of seminars for practitioners on specific topics,

— support to law enforcement networking activities to enhance exchange of information on best practices.

The abovementioned actions should cover preferably the following areas, in the context of the aspects and activities falling within the meaning of Title VI of the Treaty on European Union:

— organized crime,

— unlawful drug cultivation, production and trafficking,

— money-laundering and other types of financial crime,

— technology and crime, including the development and the use of innovative, investigative and preventative techniques (e.g. cyber-crime and interception of communications),

— prevention and combat of urban crime delinquency,

— forensic science,

— stolen vehicles,

— trafficking in nuclear and radioactive materials,

— racism and xenophobia,

— terrorism,

— arms trafficking.

NB: The Commission will be examining the projects that are submitted to it, with the assistance of experts from the relevant professional cricles. These experts will not take part in the decisions of the committee referred to in Article 11 of the Council Joint Action.

7. The budget for the year of 1997 will consist of ECU 2 500 000 (1).

It will be indicatively allocated to the different areas as follows (2):

Areas	ECU
Training	520 000
Exchange	510 000
Research	220 000
Operational projects	550 000
Meetings	700 000
Total	2 500 000

(1) ECU 2 500 000 in commitment appropriations and ECU 1 500 000 in payment appropriations. This amount is subject to authorization by the budgetary authority.

(2) The figures in this table are indicative.

8. Taking into account the late adoption by the Council, of the Joint Action (20 December 1996) establishing the programme and, with a view to ensuring a sound financial management in the implementation of the programme during its first year, the procedure for scrutiny of the applications submitted to the European Commission and pertaining to projects whose implementation should begin before the end of the current budgetary year and finish during the year following the decision to commit the funds, will be in two rounds.

For the first round, applications must be submitted before **31 March 1997.** For the second round, applications must be submitted before **15 September 1997.**

Applications for grants must be sent to the European Commission, Secretariat General, Justice and Home Affairs Task Force (Att: Mr Telmo Baltazar — N-9 6/26A), rue de la Loi/Wetstraat 200, Brussels, using the application form in one of the 11 official languages of the European Union (a translation may be added in a second working language). Forms may be obtained from the above address, tel. (32-2) 296 66 78/296 99 15; fax: (32-2) 295 01 74; e-mail (telmo.baltazar@sg.cec.be). The purpose of the project must be described as briefly and as accurately as possible at point 8 of the form, which is the only document passed on to the members of the committee referred to in Article 11 of the Council Joint Action.

An indication of the value in ecus may be attached. The budget must show the expected overall cost of the project.

The rate of support from the Community budgt may not exceed a ceiling set at 80 % of the cost of the project. In any event, the 80 % ceiling will only apply where the activity or type of activities planned are of special interest and concern a priority area in the light of the objectives of cooperation in the fields of justice and home affairs within the European Union.

No financing will be provided in respect of expenditure incurred before the decision is taken to commit the funds.

Further information may be obtained from the Background paper 'Financing of Title VI of the Treaty on European Union' which is available on request from the abovementioned address.

Beneficiaries are required to state in all advertising or published material that their projects are in receipt of financial support from the Oisin programme. Within three months of the completion of their project, they must submit a report on the execution of the project, any obstacles encountered, the assessment given by the participants, the results obtained, the dissemination of such results and the conclusions drawn.