

COMMISSION OF THE EUROPEAN COMMUNITIES

COM (79) 204 final

Brussels, 19 April 1979

DRAFT COUNCIL DECISION on the conclusion of the Agreement
on a concerted action project in the field of registration of
congenital abnormalities (medical and public health research)

(Submitted to the Council by the Commission)

COM (79) 204 final

COMMUNICATION FROM THE COMMISSION TO THE COUNCIL

● Subject : Agreement between the EEC and Greece on a concerted action project in the field of the registration of congenital abnormalities (medical and public health research)

A program of research (concerted action project) on the registration of congenital abnormalities (medical and public health research) was adopted by the Council on 13 February 1978 [†].

Article 6 of that Decision provides that the Community may conclude agreements with other States involved in European cooperation in the field of scientific and technical research (COST) with a view to extending the coordination which is the subject of that Decision to research undertaken in those States. The Commission has been authorized under the terms of that provision to enter into negotiations for the purpose stated.

On 6 October 1978, Greece expressed the wish to participate in the concerted action project concerned. Negotiations with the Hellenic Republic have led to a draft agreement which is set out in an annex to the attached draft Council decision.

This agreement provides that:

- the official responsible for coordinating the national contribution from Greece to the concerted action programme shall be a member of the Concerted Action Committee on the Registration of Congenital Abnormalities
- the financial contribution made to the coordination costs by Greece shall be 22 000 EUA for the period referred to in Article 1 of the Agreement.

The Commission requests the Council to adopt the draft decision on the conclusion of the agreement relating to a concerted action project in the field of the registration of congenital abnormalities (medical and public health research).

[†] J.O. N° L 52, p. 20 of 23.2.78.

DRAFT COUNCIL DECISION ON THE
CONCLUSION OF THE AGREEMENT ON
A CONCERTED ACTION PROJECT IN
THE FIELD OF REGISTRATION OF
CONGENITAL ABNORMALITIES (ME-
DICAL AND PUBLIC HEALTH RE-
SEARCH)

The Council of the European Communities,

having regard to the Treaty establishing the European Economic Community,

having regard to Council Decision 78/167/EEC of 13 February 1978 adopting a European Economic Community concerted action project in the field of registration of congenital abnormalities (medical and public health research)⁽¹⁾, and in particular Article 6 (1) thereof,

having regard to the draft decision submitted by the Commission,

whereas, pursuant to Article 6 (2) of Decision 78/167/EEC, the Commission has negotiated an Agreement with the Republic of Greece with a view to extending the coordination which is the subject of the abovementioned decision to research undertaken in that State,

whereas that Agreement should be approved,

HAS DECIDED AS FOLLOWS :

Article 1

The Agreement between the Community and the Republic of Greece on a concerted action project in the field of registration of congenital abnormalities (medical and public health research) is hereby approved on behalf of the Community.

The text of the agreement is annexed to this Decision.

(1) OJ N° L 52/20 of 23.2.78

Article 2

The President of the Council is hereby authorized to designate the persons empowered to sign the agreement in order to bind the Community.

Done at

Date

For the Council,
the President

AGREEMENT BETWEEN THE COMMUNITY AND THE REPUBLIC OF GREECE
ON A CONCERTED ACTION PROJECT IN THE FIELD OF REGISTRATION
OF CONGENITAL ABNORMALITIES (MEDICAL AND PUBLIC HEALTH RESEARCH)

The European Economic Community, hereinafter referred to as "the Community", and the Republic of Greece, hereinafter referred to as the "participating non-member state",

Whereas a European concerted research project in the field of registration of congenital abnormalities is likely to contribute effectively to the optimal health of the individual and of society;

Whereas, by its Decision of 13 February 1978, the Council of the European Communities adopted a Community concerted project in the field of registration of congenital abnormalities (medical and public health research);

Whereas the Member States of the Community and the participating non-member state, hereinafter referred to as "the States", undertake research in the field listed in Annex A and consider that coordination of this research will be of mutual benefit;

Whereas the implementation of the research covered by the concerted action project will require a financial contribution of approximately 900 000 European units of account from the States

HAVE AGREED AS FOLLOWS:

Article 1

The Community and the participating non-member State, hereinafter referred to as the "contracting parties", shall participate for a period extending until 31 December 1980 in a concerted action project in the field of registration of congenital abnormalities (medical and public health research).

This project shall consist in coordinating the Community concerted action programme and the corresponding programme of the participating non-member State. The programmes covered by this Agreement are listed in Annex A.

The States shall remain responsible for the research executed by their national institutions or bodies.

Article 2

The Commission of the European Communities, hereinafter referred to as the "Commission", shall be responsible for the coordination.

It shall be assisted in this task by a Project Leader.

Article 3

In order to facilitate the execution of the project, the Concerted Action Committee on the Registration of Congenital Abnormalities, hereinafter referred to as "the Committee", set up by the Decision of the Council of the European Communities of 13 June 1978, shall be extended to include the participating non-member State.

The Secretariat of the Committee shall be provided by the Commission.

The terms of reference and the composition of the Committee shall be as set out in Annex B.

Article 4

The maximum financial contribution by the contracting parties to the coordination costs shall be:

- 330 000 European units of account from the Community for a three year period beginning on 1 January 1978
- 22 000 European units of account from the participating non-member State for the period referred to in the first paragraph of Article 1.

The European unit of account shall be as defined in the financial regulation in force applicable to the General Budget of the European Communities and in the financial provisions adopted pursuant thereto.

The rules governing the financing of the Agreement are set out in Annex C.

Article 5

- 1) The States shall, in accordance with a procedure laid down by the Commission in agreement with the Committee, exchange regularly all relevant information concerning the execution of the research covered by the project, supplying the Commission with all information of use in ensuring coordination. They shall also endeavour to provide the Commission with information on research in the field in question planned or carried out by bodies not subject to their authority. This information shall be treated as confidential if the State which provides it so requests.

- 2) The Commission shall prepare yearly progress reports on the basis of the information supplied and shall forward them to the States.
- 3) At the end of the period of concerted action, the Commission shall forward to the States a report on its execution and the results obtained. This report shall be published by the Commission six months after it has been forwarded, unless a State objects. In that case, the report shall be regarded as confidential and shall be forwarded, on request, solely to the institutions and undertakings whose research or production activities justify access to the results of the research covered by the concerted action project.

Article 6

- 1) Each of the contracting parties shall, after signing this agreement, notify the Secretary-General of the Council of the European Communities as soon as possible of the completion of the procedures necessary under its internal provisions for the implementation of this Agreement.
- 2) This Agreement shall enter into force on the first day of the month following that in which the second of the contracting parties forwards this notification.

The participating non-member State may take part in the work of the Committee, without voting rights, for a period of nine months after the signature of this Agreement.

- 3) For a period of six months following its entry into force, this Agreement shall be open for accession by other European States which took part in the Ministerial Conference held in Brussels on 22 and 23 November 1971. The instruments of accession shall be deposited with the Secretary-General of the Council of the European Communities.

A State which accedes to this Agreement shall become a contracting party within the meaning of Article 1 on the date of deposit of the instrument of accession. It shall contribute to the coordination costs under the conditions laid down in Article 4 concerning the participating non-Member State.

- 4) The Secretary-General of the Council of the European Communities shall notify each of the contracting parties of the deposit of the notifications provided for in paragraph 1, of the date of entry into force of this Agreement and of the deposit of the instruments of accession provided for in paragraph 3.

Article 7

This Agreement, drawn up in a single original in the Danish, Dutch, English, French, German and Italian languages, each text being equally authentic, shall be deposited in the archives of the General Secretariat of the Council of the European Communities, which shall transmit a certified copy to each of the contracting parties.

Done at

date :

For the European Economic Community

For the Government of the Republic of Greece

Programmes covered by the Agreement

1. Registration of congenital malformations as well as of inherited biochemical and chromosome abnormalities in selected regions of the contracting parties. Registration will progressively extend to abnormalities of the nervous system (anencephaly, spina bifida, etc.), Down's syndrome, gross abnormalities of the limbs, multiple abnormalities, phenylketonuria and coeliac disease.
2. Registration of twins and multiple pregnancies in selected regions of the contracting parties.
3. Relevant methodological studies to obtain optimum coordination of existing national register and registration procedures.

The coordination will include the following regional registers of the States :

Belgium	Bruges and Hainaut
Denmark	Odense
France	Paris
Federal Republic of Germany	Hessen
Ireland	Dublin and Galway
Italy	Florence and Rome
Luxembourg	Luxembourg
Netherlands	Leidschendam
United Kingdom	Belfast, Glasgow and Liverpool
Greece	Athens

These States will contribute research under the three topics mentioned above.

TERMS OF REFERENCE AND COMPOSITION OF THE CONCERTED
ACTION COMMITTEE ON THE REGISTRATION OF CONGENITAL
ABNORMALITIES

1. The Committee shall :
 - 1.1 contribute to the optimum execution of the project by giving its opinion on all aspects of its execution;
 - 1.2 evaluate the results and draw conclusions as to their application;
 - 1.3. ensure the exchange of information referred to in Article 5 of the Agreement;
 - 1.4 Keep abreast of national research being done in the fields covered by the concerted project and more especially of scientific and technical developments likely to affect the execution of the project;
 - 1.5. suggest guidelines to the project leader.
2. The Committee's reports and opinions shall be forwarded to the Commission and to the States. The Commission shall forward these opinions to the CREST.
3. The Committee shall be composed of persons responsible for coordinating the national contributions to the programme, and the project leader. Each delegate may be accompanied by experts.

Financing rules

- I. These provisions lay down the financing rules referred to in Article 4 of the Agreement relating to a concerted action project in the field of registration of congenital abnormalities (medical and public health research)

- II. At the beginning of each financial year, a call for funds shall be issued by the Commission to the participating non-member State. Such calls for funds shall express the contribution of the non-member State in question both in European units of account and in the currency of the non-member State, the value of the European unit of account being as defined in the Financial Regulation applicable to the General Budget of the European Communities and determined on the date of the call for funds.

The participating non-member State shall pay its contribution to the Agreement at the beginning of each year, and by 31 March at the latest. The total contribution shall amount to a maximum of 22 000 European units of account.

On any sum unpaid by that date, interest shall be charged at a rate equal to the highest discount rate in the States in force on the due date. This rate shall be increased by 0.25 of a point per month of the payment being overdue. The rate thus increased shall apply to the entire period of overdue payment.

- III. The funds accruing from the contribution of the participating non-member State shall be credited to this concerted action project by being entered in the statement of revenue of the budget of the Commission as receipts within the meaning of the second subparagraph of Article 90(4) of the Financial Regulation of 21 December 1977 applicable to the General Budget of the European Communities.

- IV. The provisional timetable for the coordination costs referred to in Article 4 of the Agreement is set out in the Annex.

V. The Financial Regulation in force applicable to the General Budget of the European Communities shall apply to the management of the appropriations; furthermore, the Commission shall ensure that such appropriations are managed in conformity with the rules of the implementation of the Budget.

VI. At the end of each financial year, a statement of appropriations for this project shall be prepared and transmitted to the participating non-member State for information.

PROVISIONAL TIMETABLE FOR THE COORDINATION OF THE
 CONCENTED ACTION PROJECT ON REGISTRATION OF CONCENTRAL ABNORMALITIES (in EIA)

Annex to ANNEX C

Budget Item 3371 "Implementation of concerted action projects"

in EIA

	1978			1979			1980			TOTAL			
	AC	AP	AF	AC	AP	AF	AC	AP	AF	AC	AP	AF	
1. Initial estimate of overall requirements (figures appearing in the timetable of commitments and in the correspondence table shown in Annex II to the Commission budget)	110.000	110.000		2.000			2.000			110.000			330.000
- Staff							2.000						
- Administrative operating expenditure				13.000			13.000			110.000			330.000
- Contracts				95.000			95.000						
TOTAL (to be covered by appropriations under Item 3371)	110.000	110.000		110.000			110.000			110.000			330.000
2. Revised estimate of expenditure taking into account additional requirements arising from the accession of participating non-member State				2.000			2.000						
- Staff							2.000						
- Administrative operating expenditure				13.000+			13.000+			110.000+			330.000+
- Contracts				5.000			5.000			11.000			22.000
				95.000+			95.000+			11.000			22.000
				6.000			6.000						
				110.000+			110.000+			110.000+			330.000+
				11.000			11.000			11.000			22.000
3. Difference between I and II to be covered by contributions from participating non-member States				11.000			11.000			11.000			22.000

