

COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 8 November 1989

Proposal for a
COUNCIL DECISION

amending Decision 86/138/EEC
concerning a demonstration project with a view to
introducing a Community system of information
on accidents involving consumer products
and fixing the financial allocation for the
last two years of its operation

(presented by the Commission)

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Explanatory memorandum

Council Decision 86/138/EEC of 22 April 1986 on the EHLASS project provided for a five-year period of operation from 1 December 1985 and experimental demonstration of a system which could later become permanent depending on the results of the experiment; the system was designed to collect information on home and leisure accidents involving consumer products in order to prepare the necessary preventive measures.

The Council was to decide on the budget for the last two years on the basis of the experience acquired in the first two years.

The basic data was to be as representative as possible of the situation at national and Community level.

A basic system was set up for the collection of data from the casualty departments of selected hospitals in each Member State, although alternative sources regarded as equivalent were allowed. Only one Member State made use of the alternative by using direct household surveys as its source of information.

Each Member State collected the information and notified it to the Commission, but the management of the project, including the exploitation of the information, was the Commission's responsibility.

As regards implementation of the system it must be pointed out that:

- the Commission presented to the Council on 23 January 1989 the report provided for in Article 3 of Council Decision 86/138/EEC. The report mentioned a number of factors to be taken into account in adjusting the project and the funds to be set aside for the period 1990-91;
- although the project was set to start on 1 December 1985 only in early 1987 did contributions of substance start to arrive, despite the fact that not all the Member States had joined the system by then;
- the only two-year period for which data was received for the purposes of the system was 1987-88. During that period 663 934 accidents were reported to the EHLASS system and some further 63 000 cases are expected for that period. Although no comparative analysis can be carried out for those two years since the samples were not equivalent (in January 1987, 22 hospitals were involved; in December, 58 hospitals), a report, "Summary of Data 87-88", is being distributed

within the Commission; it sets out a broad, overall analysis of the data in question;

- a number of Member States have prepared (or continued to prepare) annual reports on the basis of national data. This exploitation at national level has proved useful and provides an overall idea of the scope of the problem together with other sources of information; above all it serves as a "pointer" to areas in which more detailed specific investigations have revealed the need for specific preventive measures;
- 1989 is regarded as a transitional year with a view to continuing the demonstration project for the two remaining years and to enable us to draw major, significant conclusions before taking a decision.

The results obtained have shown that the following should be regarded as fundamental to continuation of the demonstration project:

- Generally speaking systems for the collection of data from hospitals at national level - their design, operation and exploitation being harmonized at national level - are considered useful (with the assistance of other existing sources of information or as a guide to more detailed investigation) with a view to the sound management of policies on product safety and consumer protection at national and ultimately consumer Community level.
- We must look into the continuing exploitation of hospital data collection systems and other sources of information at national and Community level. More particularly, the experience of one Member State with direct household surveys has shown that this technique may be used:
 - . in exceptional circumstances to extend the results of hospital data collection (including their links with other sources) and obtain complete pictures of the situation to be updated in the medium term;
 - . as a basis to orient preventive policies. If there were no permanent hospital data collection systems this would be required more frequently.
- The assessment and exploitation of the data concerning consumer safety vis à vis products must be performed first of all and as soon as possible at national level. Harmonized bases should be set up to provide for comparisons and utilization of the results by other Member States and in particular to provide for final, overall exploitation or exploitation in specific fields at Community level.

In view of the foregoing, the attached Decision aims to:

- extend the operation of the demonstration project to six years;
- determine the maximum amounts considered necessary for the operation of the project in 1990 and 1991;
- make the amendments that are essential to enable the Commission to undertake the additional work required;
- request the Member States to exploit the national data initially and produce national reports on harmonized bases to be put forward by the Commission.

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THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the treaty establishing the European Economic Community,
and in particular Article 235 thereof,

Having regard to the proposal from the Commission,¹

Having regard to the opinion of the European Parliament,²

Having regard to the opinion of the Economic and Social Committee,³

Whereas Council Decision 86/138/EEC⁴ set up a demonstration
project limited to a five-year period with a view to the possible
introduction of a Community system to collect information on the various
aspects connected with the safety of products where they are involved in
accidents and particularly on the respective roles of the product, the
victims and their surroundings at the time of the accident; whereas this
information is of major importance to consumer protection;

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⁴ OJ No L 109, 26.4.1986, p.23.

Whereas Article 3 of the Decision set the allocation for implementation of the project during the first three years; whereas the Council was to take a decision on the financial allocation required for the last two years on the basis of a report from the Commission on results obtained during the first two years;

Whereas the Commission presented that report to the Council on 23 January 1989;

Whereas the adjustment of the project needed to ensure attainment of its objectives and improved operation during the last two years requires that 1989 be regarded as a transitional year, which does not actually count for the calculation of the five-year period, and also amendments to certain provisions of Decision 86/138/EEC,

HAS ADOPTED THIS DECISION:

Article 1

Decision 86/138/EEC is hereby amended as follows:

1. In Article 1(1) the words "five years" are replaced by "six years".

2. Article 4(2) is replaced by the following:

"2. Without prejudice to paragraph 1, Member States shall be requested to exploit directly the national data collected and to prepare annual reports on the results obtained. The Commission shall draw up guidelines for harmonization of the national reports on exploitation of the data and ensure, if necessary, that they are disseminated and used at Community level.

3. The Commission shall carry out the studies it considers necessary to supplement the information collected pursuant to Article 1 and shall ensure that it is interpreted and exploited as effectively as possible.

4. In carrying out the tasks referred to in paragraphs 1, 2 and 3 the Commission shall consult the Committee referred to in Article 7."

3. In Annex I the following paragraph is added to point 2:

"The Commission may collect the additional information it considers necessary during the demonstration project".

Article 2

The maximum amount considered necessary for the Community's participation in the implementation of the project in 1990 and 1991 shall be ECU 12 million.

An indicative breakdown of this amount is set out in the Annex.

Article 3

This Decision is addressed to the Member States.

Done at Brussels

For the Council

GUIDELINES ON BREAKDOWN OF FUNDS

The following guidelines will be used in the breakdown of the amount of ECU 12 million referred to in Article 2 of the Decision:

- (a) collection of hospital data: on the basis of the current 58 hospitals (50% of which are changed each year) plus 16 new hospitals each year up to a total of 90 hospitals (ECU 5 million);
- (b) technical and administrative support at Community level and related activities (Article 4 of Decision 86/138/EEC) (ECU 1.35 million);
- (c) additional information: point 2 of Annex I to Decision 86/138/EEC (ECU 1.85 million);
- (d) Complementary studies - Art. 4.3 (ECU 3.8 million)

FINANCIAL STATEMENT

1. Budget heading

682 - EHLASS: Monitoring operations in relation to the safety of consumer products

2. Legal basis

2.1 Article 235 of the Treaty

2.2 Council Decision 86/138/EEC of 22 April 1986 concerning a demonstration project with a view to introducing a Community system of information on accidents involving consumer products.

3. Proposed classification of expenditure

Non compulsory

4. Description of measure and justification

4.1 Description

Continuation of EHLASS demonstration project based on Decision 86/138/EEC in which a financial allocation was provided for the first three years of the project's total five-year duration. The Council should decide on the funding for the last two years on the basis of the results of the first two years.

The basic measure concerns the collection of data from hospital casualty departments on accidents involving consumer products. The collection now covers 58 hospitals and is to be extended to 90 hospitals and supplemented in particular by supplementary studies in order to meet the project's objectives.

4.2 Justification

To meet the requirements of Decision 86/138/EEC and respond to the conclusions of the analysis of the results of the first stage of the project.

5. Nature of expenditure and method of calculation

1990

-	29 hospitals	x ECU 28 000	ECU 812 000
-	29 new hospitals turnover	x ECU 33 000	ECU 957 000
-	16 newly-incorporated hospitals	x ECU 33 000	<u>ECU 528 000</u>
-	TOTAL HOSPITAL EXPENDITURE		ECU 2 297 000
-	Technical and administrative support (*)		ECU 500 000
-	Additional information Annex I.2		ECU 800 000
-	Complementary studies (Art. 4.3)		<u>ECU 903 000</u>
	TOTAL.....		ECU 4 500 000

1991

-	45 hospitals	x ECU 28 000	ECU 1 260 000
-	29 new hospitals turnover	x ECU 33 000	ECU 957 000
-	16 newly incorporated hospitals	x ECU 33 000	<u>ECU 528 000</u>
-	TOTAL HOSPITAL EXPENDITURE		ECU 2 745 000
-	Technical and administrative support(*)		ECU 800 000
-	Additional information Annex I.2		ECU 1 055 000
-	Complementary studies (Art. 4.3)		<u>ECU 2 900 000</u>
	TOTAL.....		ECU 7 500 000

* (including expenditure on infrastructure relating to the internal use of external resources)

6. Financial consequences of measure on intervention appropriations

6.1 Timetable for appropriations

Item 682

	<u>Commitment appropriations (ECU)</u>	<u>Payment appropriations (ECU)</u>
1990	4 500 000	4 500 000
1991	7 500 000	7 500 000
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	12 000 000	12 000 000

6.2 The Community is financing 80% of the total cost of measures concerning data collection from hospitals and 100% of the other measures.

7. Financial consequences on staff appropriations

7.1 Staff required for implementation of the measure only

In 1990 and 1991 we will require the following officials:

- 1 A, project management
- 1 B, technical assistance, updating files
- 1 C, secretariat

The staff requirements set out above are to be met either by internal redeployment or under the budgetary procedure for the years concerned (1990 and/or 1991).

7.2 Appropriations required for staff

The appropriations required from 1990 are estimated at ECU 240 000 per year.

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Impact on competitiveness and employment

Proposal for a Council Decision amending Council Decision 86/138/EEC of 22 April 1986 concerning a demonstration project with a view to introducing a Community system of information on accidents involving consumer products and determining the financial allocation for the last two years of its operation.

1. The objective of the proposed Council Decision is to complete the EHLASS demonstration project which collects information on accidents involving consumer products.
2. The proposal provides for the continuation of measures, notably by hospitals selected by the Member States, to be supplemented by measures concerning the collection and exploitation of information carried out directly by the Commission.
3. The proposal in itself has no direct effect on branches of the economy save for possible consequences on the work carried out by hospital staff or by service firms in the field of information. However, progress in preventive policies on product safety should have favourable consequences on fairness in dealings, the competitiveness of businesses and on employment resulting from the image of Community industry as a supplier of safe products.
4. This Decision imposes no direct obligation on businesses.
5. The only indirect measures which might be imposed on businesses by national authorities would result from the detection, as a result of the data collection, of hazardous products on the market. This would have a favourable effect on the defence of the internal market, prevent unfair competition and improve consumer confidence in industrial products on a properly-supervised market. These measures could be carried out under existing legislation.

Impact on public opinion

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The development of this demonstration project and the establishment of a permanent system of statistical information on accidents involving consumer products should help to improve the standard of product safety and provide for preventive measures and the establishment of priorities, the European citizen being the prime beneficiary.

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DOCUMENTS

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