COMMISSION OF THE EUROPEAN COMMUNITIES

COM(84) 284 final

Brussels. 24 May 1984

Draft

COUNCIL RESOLUTION

on a programme of action of the European Communities
on toxicology for health protection

(submitted to the Council by the Commission)

I. INTRODUCTION

With the development of industrial society there has been an increased demand and need for health protection measures in the work place, the environment and in the production and placing on the market of goods and products.

As a result a variety of measures has been successfully undertaken at national, Community and international levels. At national level the measures have included regulations limiting use, exposure limits in the workplace and the development of poison centres. At Community level sectorial activities have sought to coordinate and initiate actions in, for example, the fields of nutrition, environment and worker protection. In pursuit of the establishment of the Common Market, in particular the free circulation of goods, it has been necessary to coordinate, harmonise and develop common Community measures. At international level the general concern has led, for example, to the setting up of the International Programme on Chemical Safety under the joint sponsorship of UNEP, ILO and WHO, the chemicals programme of OECD, the WHO/FAO joint programme and the emphasis placed on chemical carcinogenesis by the International Agency for Research on Cancer. A number of the Community actions are carried out in collaboration with the above agencies.

The Community has developed specific approaches in toxicology to deal with the problems arising in each sector and has undertaken research in a number of these areas.

At a scientific level all of these developments have led to an increasing demand on the evolving discipline of toxicology. The rate of increase, coupled with scientific advances in chemistry, physics, biology and medicine, has produced a situation whereby current and future demands are likely to overwhelm available resources leading to delay, breakdown and a reduction in quality of toxicity testing and toxicovigilence.

II. AIMS OF THE PROGRAMME

The programme is aimed at general issues in toxicology and seeks to provide support to the development of sectorial activities. The objective is to improve current practice and thereby:

- make efficient and economic use of the limited resources available

- seek to integrate the use of experimental, clinical and analytical toxicological data establishing normal functioning of organs against which experimental and clinical toxicological information can be assessed

- assist the development of the discipline improving the standard and availability of toxicologists in the Community

Currently toxicological activities are expanding rapidly in Member States and all industrialised countries. It is, therefore, particularly necessary to seek to avoid duplication of effort and any requirement for a use of inappropriate measures.

An integrated approach to health risk assessment can only be based on a better information flow. This should be promoted by improving the uniformity and quality of data together with agreement as to the manner of interpreting the findings.

The programme should also have a beneficial consequence on animal welfare, without lowering the quality of toxicity data. Avoiding as far as possible any duplication of testing will reduce the numbers of test animals and collaboration should facilitate the adoption of new methods of testing wherever appropriate.

III. DESCRIPTION OF SPECIFIC ACTIONS

A number of actions have been identified to form the basis of this programme. They are divided into the following three sections:

- Toxicological practice
- Clinical toxicology
- Training and information

Toxicological Practice

In Member States the resources for toxicology testing are limited in terms of manpower, means and facilities. It is therefore important to avoid unnecessary duplication of efforts and this will be attempted through the compilation of ongoing toxicological testing facilities and activities, taking account of the confidentiality aspect.

An objective evaluation of health hazards requires that the quality and comparability of experimental and clinical analytical data be ensured. This would facilitate the transfer and acceptability of information between Member States.

Clinical Toxicology

Clinical toxicology combines clinical diagnosis with the application of toxicological and analytical methodologies followed by subsequent treatment procedures. In the case of emergency, to ensure a rapid screening of persons exposed, the clinical diagnostic and analytical methods must be able to provide a rapid answer and the treatment methods should ensure an effective and rapid response. Their improvement should therefore be promoted.

A large amount of clinical data exists in poison centres, clinical toxicological services and other health services. An effort should be made to improve the collection and analysis of these data, having due regard for the need of medical confidentiality, so as to provide a better appreciation of toxicological hazards.

Prevention of the toxic effects of chemicals requires the early detection of deviations from normal function of specific tissues and organs which are of predictive value. The current practice in Member states and scientific basis for defining the normal functioning of organs will be considered to determine the significance of deviations in function, their impact on health and their relevance to exposure to agents. An approach at Community level for these basic problems should help provide more consistent assessments of the impact on health of various agents and a better definition of the state of health within the framework of Article 36 of the Treaty.

Training and Information

At Community level the problem of manpower needs and training in toxicology must be considered. It is necessary to calculate future needs taking into account the trainings available and existing and future career opportunities. Training in toxicology for other professions involved with chemical safety is also important. Exchange of toxicologists between Member States should provide a rapid means for promoting the harmonisation of toxicological investigations and of concepts for toxicological appraisals and health risk evaluations.

Information on toxicological hazards must be objective, making the public aware of risks but avoiding unnecessary public alarm. Ways and means of making appropriate validated toxicological information more widely available must be considered.

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Draft Council resolution on a programme of action of the European Communities on toxicology for health protection

COM(84) 284 final

(Submitted by the Commission to the Council on 29 May 1984)

(84/C 156/06)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaties establishing the European Communities,

Having regard to the draft resolution submitted by the Commission,

Having regard to the opinion of the European Parliament,

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

Whereas the Council resolution of 21 January 1974 concerning a social action programme [1] takes note of the social action programme of the Commission which provides for the formulation of proposals concerning the protection of the health of populations;

Whereas, under Article 2 of the Treaty establishing the European Economic Community, the Community shall have in particular as its task, by establishing a common market and progressively approximating the economic policies of Member States, to promote throughout the Community a harmonious developing of economic activities, a continuous and balanced expansion and an accelerated raising of the standard of living;

Whereas, at the conference held in Paris in October 1972, the Heads of State or of Government affirmed that the first aim of economic expansion, which is not an end in itself, should be to enable disparities in living conditions to be reduced and that it should result in an improvement in the quality of life as well as in the standard of living;

Whereas toxicology as a discipline has become established in recent years and has contributed significantly to the protection of health;

Whereas a number of sectorial activities, such as those involving pharmaceuticals, cosmetics, human and animal foodstuffs, environmental chemicals, pesticides, occupational exposure to chemicals, already benefit from toxicological information and are assisted by a number of scientific advisory committees;

Whereas the various scientific research programmes of the European Community cover from the research point of view several areas of the present programme and will provide therefore a valuable input of new knowledge;

Whereas the present programme will assist the development of clinical toxicology and the integration of experimental, clinical and analytical data;

Whereas the present programme, by ensuring the quality and comparability of data and by identifying testing facilities and on-going testing programmes, should help promote a more rational and economic use of the toxicological testing facilities in the European Community;

Whereas the assessment of normal variability in the functioning of tissues and organs should help to define the term 'health' as referred to in Article 36 of the EEC Treaty; the present programme, by ensuring the quality and comparability of data and of testing methods, is likely to contribute to the elimination of certain obstacles to trade where those obstacles are based on considerations of health;

Whereas there is a need to have sufficient resources in the European Community for toxicological evaluation and the level of toxicological awareness should be enhanced;

Whereas this programme should help avoid unnecessary testing on laboratory animals;

Whereas the Toxicology Section of the Scientific Advisory Committee on Toxicology and Ecotoxicology established by the Commission in 1978 should provide scientific advice to this programme;

Whereas cooperation with the various international agencies having activities in this area and in particular the World Health Organization (WHO), the United Nations Environment Programme (UNEP) and the International Labour Organization (ILO) through their joint International Programme on Chemical Safety, as well as the International Agency for Research in Cancer (IARC) and the Organization for Economic Cooperation and Development (OECD), is essential to avoid duplication of efforts;

[1] OJ No C 13, 12. 2. 1974, p. 1.

EXPRESSES THE POLITICAL WILL:

to take, in keeping with the urgency of the matter and bearing in mind what is feasible at national and Community level, the measures required so that between now and the end of 1990 the following priority actions in particular can be undertaken:

1. **Toxicological practice**

   Determine the feasibility of compiling and maintaining a register of toxicity testing facilities in Member States. Undertake assessments of current methods and practice in order to improve the quality and comparability of toxicological data and to facilitate their acceptability.

2. **Clinical toxicology**

   Review the role and functioning of poison centres and related clinical toxicological services: organize exchanges of experience and information and develop the use of their data for epidemiological and statistical purposes.

   Review current practice in the assessment of normal variability of biochemical and physiological parameters and recommend common standards.

3. **Training and information**

   Evaluate manpower needs for toxicology and make recommendations for training requirements: promote the exchange of expertise and information between Member States.

REQUESTS THE COMMISSION:

to prepare annually, after consulting Member States, a forward outline of the work it intends to carry out on the implementation of this resolution.

FINANCIAL STATEMENT

1) Budget heading :

6484 - Programme of action on toxicology for health protection (included in the 1985 preliminary draft budget).

2) Legal basis :

Article 2 of the Treaty.

3) Proposal for classification under compulsory/non-compulsory expenditure :

Non-compulsory.

4) Description and justification of project :

The programme is aimed at general issues in toxicology and seeks to provide support to the development of sectorial activities. The objective is to improve current practice and thereby:

- make efficient and economic use of the limited resources available
- seek to integrate the use of experimental, clinical and analytical toxicological data establishing normal functioning of organs against which experimental and clinical toxicological information can be assessed
- assist the development of the discipline improving the standard and availability of toxicologists in the Community

Currently toxicological activities are expanding rapidly in Member States and all industrialised countries. It is, therefore, particularly necessary to seek to avoid duplication of effort and any requirement for a use of inappropriate measures.

An integrated approach to health risk assessment can only be based on a better information flow. This should be promoted by improving the uniformity and quality of data together with agreement as to the manner of interpreting the findings.

The programme should also have a beneficial consequence on animal welfare, without lowering the quality of toxicity data. Avoiding as far as possible any duplication of testing will reduce the numbers of test animals and collaboration should facilitate the adoption of new methods of testing wherever appropriate.

5) Type of expenditure and method of calculation :

Expenses for studies, training courses, experts and consultants, related meetings and secretarial expenses, missions and subsidies, publications and the purchase of scientific works and periodicals are charged against this item.

Method of calculation for 1985

- Travel and other expenses for meetings, conferences, seminars and missions	60 000
- Experts', consultants' and study fees	100 000
- Subsidies and secretarial expenses	25 000
- Publications and purchase of scientific works	15 000
	200 000

6) Financial implications for intervention appropriations :

6.1 Initially the programme is scheduled to last five years. The financial estimates are based on the programme being initiated in 1985 and becoming fully operational in 1986.
After 1986, a regular 10% increase is foreseen.

	Commitment appropriations (Ecu)	Payment appropriations (Ecu)
1985	200 000	200 000
1986	350 000	350 000
1987	385 000	385 000
1988	420 000	420 000
1989	455 000	455 000
	1 810 000	1 810 000

6.2 Proportion (%) financed from the Community budget :

100%

7) Remarks :

Nil

8) Financial implications for staff and current administrative appropriations :

8.1 Staff working exclusively on the project :

3 As, 1 B, 3 Cs.

8.2 Appropriations to cover the above staff :

Since part may be drawn from the appropriations for existing staff, only :

2 A/5-6, 1 B/2-3 and 2 C/3-4 are required.

Cost per year (ECUs) :

2 A/5-6	118 208
1 B/2-3	46 460
2 C/3-4	57 184
Total	221 852