

COMMISSION OF THE EUROPEAN COMMUNITIES

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Draft

COUNCIL RESOLUTION

on improving the prevention and treatment of acute human poisoning

(presented by the Commission)

EXPLANATORY MEMORANDUM

In 1986 the Council adopted a Resolution on a programme of action of the European Communities on toxicology for health protection (OJ C 184/1 and 2 of 23 July 1986), involving a systematic review of the role and functioning of poison centres in order to develop the use of clinical toxicology data (acute and chronic) within the framework of an overall assessment of the impact of chemical products and preparations on human health, as well as to promote the exchange of expertise and information between Member States on toxicological data.

Acute intoxications in man constitute a medical challenge and a serious public health problem in the Community. A serious public health problem in that the causes of intoxications are diverse, constantly increasing in number, and able to circulate freely in the Community. The latter aspect will become even more applicable when the Single Market is established in 1993. The poison centres of one country are not necessarily in a position to identify the toxic substances contained in preparations from another Member State. Another serious cause for concern is the possibility of a major poisoning disaster where diagnosis may be easy, but the large number of persons affected (workers and members of the public) may cause problems with the supply of antidotes.

Acute intoxications represent a medical challenge in that the poison centres which are then contacted must, in the vast majority of cases, reply immediately by telephone to often badly formulated questions from members of the public, as well as from medical staff. They must then make a diagnosis on the basis of the information given, and may also have to prescribe treatment.

It was in this light that the Commission carried out a major survey on the functioning of poison centres in the Community and sent a questionnaire on the availability of antidotes to the Member States.

From the replies it emerged that there is a certain amount of disparity in how the poison centres process questions and information on intoxications. It was also found that even specialized institutions were relatively ignorant of some of the less commonly used antidotes.

The Commission is therefore proposing a series of measures to harmonize the collection of data and annual reports and to improve the availability of antidotes, paying special attention to the border zones of the Member States, where trade is more intensive and information more necessary.

These measures will help "to promote throughout the Community a harmonious development of economic activities and closer relations between the States belonging to it" (Article 2 of the EEC Treaty) by anticipating and reducing the possible effects of certain preparations containing potentially dangerous substances on the health of workers and the public.

AIMS OF THE DRAFT RESOLUTION

This Draft Resolution should make it possible to prevent and treat acute poisoning in a more effective way on the basis of the experience of the poison centres; it provides for the following:

- harmonized collection and summarizing of information;
- cooperation between the poison centres in areas adjacent to other Member States;
- the improvement of the availability of antidotes;
- assessment at Community level of steps taken to prevent acute poisoning.

CONSULTATION OF THE OTHER INSTITUTIONS

It would be desirable to have the opinion of the European Parliament.

OPINION OF THE SCIENTIFIC ADVISORY COMMITTEE

The Scientific Advisory Committee responsible for examining the toxicity and ecotoxicity of chemical compounds expressed a favourable opinion on the harmonized annual reports (1).

(1) OJ No L 198, 22.07.78, p. 17
OJ No L 105, 26.04.88, p. 29

COUNCIL RESOLUTION

ON IMPROVING THE PREVENTION AND
TREATMENT OF ACUTE HUMAN POISONING

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the Draft Resolution submitted by 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, for a policy aimed at preventing the risks of acute poisoning in the population and, in particular, among workers, it is desirable to have the maximum amount of comparable data on clinical toxicology at Community level;

Whereas each poison centre in the Community, by virtue of its informational, therapeutic and analytical functions, is one of the bodies in the best position to collect clinical toxicology data in its geographical area of activity and to process this information;

Whereas a harmonization of the procedures for collecting clinical toxicology data for all the poison centres in the Community would facilitate the development of a policy for toxic risk prevention;

Whereas, by fostering the integration of clinical and analytical data, the Community wishes to achieve one of the main objectives of its programme of action on toxicology for health protection (4), namely to help ensure the quality and comparability of data and encourage the exchange of experience and information in the field of clinical toxicology;

(1) ...

(2) ...

(3) ...

(4) OJ No C 184, 23.07.1986, p 1

Whereas harmonized annual reports will also be of value in the context of the Council Decision of 22 April 1986 (86/138/EEC) (5) concerning a demonstration project with a view to introducing a Community system of information on accidents involving consumer products, which stipulates in Annex I (sub-section 2, paragraph 3) that additional information may be obtained from poison centres to supplement the basic information obtained from the casualty departments of hospitals;

Whereas, in the context of the free movement of persons and goods, it is important to improve the availability of antidotes by facilitating exchanges of information on their availability, in particular in areas adjacent to other Member States;

Whereas this Resolution should help to develop the use of clinical toxicology data in overall assessments of the impact of chemical products and preparations on the health of the public in general and, more particularly, of workers exposed to dangerous substances liable to cause acute poisoning,

I

Expresses the political will to take the necessary steps to improve the prevention and treatment of acute human poisoning;

II

Invites the Member States:

- to designate a competent authority so that it may take the necessary measures to ensure that the collection of call data and the annual reports on the work of the poison centres and the associated toxicology services operating in the territory of the Member State concerned are based on the indications set out in Annexes 1 and 2;
- to ensure that antidotes, i.e. the substances and preparations used specifically in cases of acute poisoning, are available on the territory of the Member State concerned;
- to increase the practical scope for using antidotes on the territory of the Member State concerned by requiring the competent authority to prepare and distribute a list, based on Annex 3, of available antidotes for treating acute poisoning cases and of sources of supply, so that the recipients have at their disposal the information required to obtain these antidotes within the period during which they can be administered effectively;

(5) OJ No L 109, 26.04.86, p 23

- to provide better emergency services in areas adjacent to other Member States by arranging for the relevant competent authorities, in cooperation with the Commission, to set up between the poison centres a Community system of information and collaboration concerning the availability of antidotes;
- to arrange for the competent authority to produce a summary of the harmonized annual reports of the poison centres and the associated toxicology services. This summary will deal in particular with records of poisoning, with a note on the measures taken or planned by the competent authority to improve the prevention of acute poisoning, and shall be forwarded to the Commission before 31 March of the following year, together with a list of the poison centres operating on their territory showing the areas which they cover, and the list of available antidotes. The Commission may, where necessary, arrange for all or part of the harmonized annual reports to be forwarded to it;

III

Invites the Commission to arrange for regular summary reports to be prepared for the Community indicating, in particular, the measures required at Community level for the prevention of acute poisoning, and to expand on specific topics based on the information received from the Member States on the prevention and treatment of acute poisoning;

IV

Agrees to review the provisions of this Resolution within a maximum period of five years following its adoption, on the basis of a report from the Commission.

HARMONIZED CASE DATA RECORD SHEET

1. Centre code : 2. Call registration number :
Recall : ()

3. 3.1 Date (mmdd) : 3.2 Time (hhmm) :

4. 4.1 Enquirer : Name :
Address :
Tel Number :

4.2 Type of enquirer

4.2.1 Hospital :

- Accident and Emergency (Casualty) ()
- General Medical ()
- Intensive Care ()
- Paediatric ()
- Other ()
- Unknown ()

Other Poisons Centres ()

4.2.2 Outside hospital :

- Physicians ()
- Nurses ()
- Pharmacists ()
- Veterinary surgeons ()
- Occupational health services ()
- Industry/manufacturers ()
- Emergency Services ()
- General Public ()
- Mass Media ()
- Authorities ()
- Others ()
- Unknown ()

5. Type of enquiry

Call related to a case () Information only () Other () Unknown ()

6. Patient 6.1 Multiple cases : Yes; Number :

6.2 Human : Name :

6.2.1 Age (yyymmdd) :; if estimated ()
Unknown Child () Unknown Adult () Unknown ()

6.2.2 Sex : Male () Female ()

6.2.3 Weight (kg) : ; if estimated ()

6.2.4 Pregnant : Duration (weeks) :

6.2.5 Lactating : yes ()

6.3 Animal species :

7. Agents

Classification of product

Annual : Poisons

Report : Centre

7.1 Name (given by caller) : : :
Composition of product : : :
..... : :
Manufacturer (if relevant) : : :
Quantity : N° : ... ; Vol. : ; Wt. :, if estimated ()
Unknown ()
Exposure : Acute () ; Chronic ()
Frequency : Single () ; Repeated ()

7.2 Name (given by caller) : : :
Composition of product : : :
..... : :
Manufacturer (if relevant) : : :
Quantity : N° : ... ; Vol. : ; Wt. :, if estimated ()
Unknown ()
Exposure : Acute () ; Chronic ()
Frequency : Single () ; Repeated ()

7.3 Name (given by caller) : : :
Composition of product : : :
..... : :
Manufacturer (if relevant) : : :
Quantity : N° : ... ; Vol. : ; Wt. :, if estimated ()
Unknown ()
Exposure : Acute () ; Chronic ()
Frequency : Single () ; Repeated ()

7.4 Name (given by caller) : : :
Composition of product : : :
..... : :
Manufacturer (if relevant) : : :
Quantity : N° : ... ; Vol. : ; Wt. :, if estimated ()
Unknown ()
Exposure : Acute () ; Chronic ()
Frequency : Single () ; Repeated ()

7.5 Name (given by caller) : : :
Composition of product : : :
..... : :
Manufacturer (if relevant) : : :
Quantity : N° : ... ; Vol. : ; Wt. :, if estimated ()
Unknown ()
Exposure : Acute () ; Chronic ()
Frequency : Single () ; Repeated ()

7.6 Time since exposure : (ddhmm)

8. Location

- 8.1 Home and surroundings ()
- 8.2 Workplace :
 - Factory/workshop ()
 - Laboratory ()
 - Agriculture/horticulture ()
 - Other ()
- 8.3 Community :
 - Nursery or primary school ()
 - Other school, univ, educational establishment ()
 - Hospital, clinic, nursing home ()
 - Institution : prison, military, etc ()
 - Other ()
- 8.4 Enclosed public spaces ()
- 8.5 Open places ()
- 8.6 Other ()
- 8.7 Unknown ()

9. Circumstances

- | | | |
|------------------------------|------------------------|----------------------|
| 9.1 Accidental/Unintentional | 9.2 Intentional | 9.3 Adverse reaction |
| General () | Suicide () | Drug () |
| Occupational () | Misuse () | Food () |
| Environmental () | Abuse () | Other () |
| Transport Accident () | Malicious/criminal () | |
| Fire () | Other () | |
| Therapeutic error () | Unknown () | |
| Misuse () | | |
| Other () | | |
| Unknown () | | |
- 9.4 Unknown ()

10. Route of exposure

- 10.1 Ingestion ()
- 10.2 Inhalation ()
- 10.3 Cutaneous ()
- 10.4 Eye contact ()
- 10.5 Bite ()
- 10.6 Sting ()
- 10.7 Injection
 - Subcutaneous ()
 - Intramuscular ()
 - Intravenous ()
 - Intra-arterial ()
- 10.8 Mucosal
 - Buccal ()
 - Nasal ()
 - Rectal ()
 - Vaginal ()
- 10.9 Placental ()
- 10.10 Other
- 10.11 Unknown

LAYOUT OF THE HARMONISED ANNUAL REPORTS

1. Identification of the body drafting the report

Name; full address (indicating country); telephone, telex and fax numbers (if any); name of person in charge of centre.

2. Year

The year covered by the annual report in question.

3. Administrative information on the centre

Description of staff at centre (medical and administrative personnel); a brief description of the centre's work; the size of the population served.

4. Calls to the centre

The total number of calls, their monthly variation, their distribution according to the person making the request, the way in which the call is made (telephone, letter, etc.), the reasons (actual or presumed poisoning, simple request for information, etc.).

5. Poisoning cases

- the number of cases and the frequency should be indicated for each category or sub-category;
- if the centre has the necessary resources, it would be desirable to break down the data in terms of the classes of aetiological agents listed below.

5.1 Cases involving human beings

- males, females (including pregnant women, nursing mothers), unspecified
- Age groups (in years):
 - < 1
 - 1 - 4
 - 5 - 9
 - 10 - 14
 - 15 - 19
 - 20 - 69
 - > 70
 - unknown

- Aetiological agents:

- . non-pharmaceutical chemical substances (simple or compound, natural or synthetic):
 - industrial
 - pesticides
 - household products
 - others
- . pharmaceutical substances (human or veterinary)
- . animals as such (whether by their venom or through consumption of poisonous meat - e.g. ichthyosarcotoxism - where chemical products, bacteria or putrefaction are not the cause)
- . plants as such (including hallucinogenic or poisonous mushrooms)
- . others (including toxins of bacterial origin, e.g. botulism)
- . not identified

- Location:

- . home and immediate surroundings
- . workplace : . industry
 - . agriculture/horticulture
 - . other
- . public establishments (e.g. schools or training centres, government offices, post offices, libraries, public transport - trains, buses, underground railways, etc.)
- . enclosed public places (e.g. bars, discotheques, restaurants, shopping centres, department stores, etc.)
- . open places (e.g. sports grounds, children's playgrounds, etc.)
- . other or unknown

- Circumstances:

- . accidental acute poisoning
- . deliberate acute poisoning
- . side effect of drugs
- . accidental chronic poisoning
- . deliberate chronic poisoning
- . other or unknown

- Initial evaluation:

- . non-toxic
- . probably non-toxic
- . poisoning not excluded
- . predictable risk
- . established poisoning
- . symptoms unrelated to the exposure

- Treatment:

- . none
- . symptomatic only
- . specific (antidote therapy).

- Outcome

- . complete recovery
- . hospitalization (number of days)
- . sequelae
- . death
- . unknown

5.2 Animals

6. Record of poisoning cases

Draw up a list of the fifteen most frequent causes of poisoning in decreasing order of frequency (indicating the number of calls), with a breakdown by age group.

7. Record of requests for information

Draw up a list of the fifteen products for which most requests for information are received.

8. Record of toxicological analyses

Draw up a list of the fifteen toxicological analyses which are most frequently requested by the centre.

9. Comments in free text

On all treatment given and information provided; on particularly interesting cases which may have been encountered, on other activities (teaching, research, etc.) and on any other aspect not included elsewhere.

10. Conclusions

These are to deal mainly with the impact of the centre's activities on prevention.

ANNEX 3

INDICATIVE LIST OF ANTIDOTES

A. SPECIFIC ANTIDOTES

ANTIDOTE	MAIN INDICATIONS	AVAILABILITY IN TERMS OF URGENCY OF USE IN TREATMENT
Acetylcysteine	Paracetamol	B
	Chloroform	B
	Carbon tetrachloride	B
	Acrylonitrile	B
Amyl nitrite	Cyanide	A
Antivenins and antoxins		A-C
Atropine	Cholinergic syndrome	A
Benzylpenicillin	Amatoxins	B
Calcium gluconate	Hydrofluoric acid	A
	Fluorides	A
	Oxalates	A
Calcium sodium edetate (EDTA)	Lead	B
Dantrolene	Malignant Hyperthermia	A
	Malignant Neuroleptic Syndrome	A
Deferoxamine	Iron	B
	Aluminium	B
Diazepam	Seizures	A
	Chloroquine	A
Dicobalt Edetate	Cyanide	A
Digoxin specific antibody fragments (FAB)	Digoxin	B
	Digitoxin	B
	Digitalis Glucosides	B

A: required to be immediately available (within 30 minutes)

B: required to be available within two hours

C: required to be available within six hours

SPECIFIC ANTIDOTES	MAIN INDICATIONS	AVAILABILITY IN TERMS OF URGENCY OF USE IN TREATMENT
Dimercaprol (BAL)	Arsenic Gold, inorganic mercury Lead encephalopathy	B B B
4-Dimethylaminophenol (4-DMAP)	Cyanide	A
Diphenhydramine	Drug-induced dystonias	A
Ethanol	Methanol Ethylene glycol	A A
Etybenzotropine	Drug-induced dystonias	A
Flumazenil	Benzodiazepines	B
Folinic Acid	Folic Acid Antagonists	A
Glucagon	-blockers	A
Hydroxocobalamin (Vit. B12a)	Cyanide	A
Methionine	Paracetamol	B
4-Methylpyrazole	Ethylene glycol Methanol	A A
Methylthioninium chloride (Methylene blue)	Methaemoglobinaemia	A
N-Acetyl penicillamine	Mercury (organic and metallic)	C
Naloxone	Opiates	A
Neostigmine	Neuromuscular block (curare type) Peripheral anticholinergic poisoning	A A
Oximes	Organophosphates	B
Oxygen	Carbon monoxide Cyanide Hydrogen sulphide	A A A
Oxygen hyperbaric	Carbon monoxide Cyanide Hydrogen sulphide Carbon tetrachloride	C C C C

SPECIFIC ANTIDOTES	MAIN INDICATIONS	AVAILABILITY IN TERMS OF URGENCY OF USE IN TREATMENT
D-Penicillamine	Copper Gold, Lead, Mercury (elemental) Zinc	C C C
Pentetic Acid (DTPA) Diethylenetriamine pentaacetic acid	Plutonium, actinides	A
Phentolamine	Alpha-adrenergic poisoning	A
Physostigmine	Central anticholinergic syndrome from - atropine and derivatives - other drugs	A A
Phytomenadione (Vit K)	Coumarin and indanedione anticoagulants	B
Potassium ferric hexacyanoferrate (Prussian Blue)	Thallium	B
Prenalterol	-blockers	A
Protamine sulphate	Heparin	A
Pyridoxine (Vit. B6)	Isoniazid Crimidine Ethylene glycol Gyromitrin Hydrazines	A B B B B
Silibinin	Amatoxins	B
Sodium nitrite	Cyanide	A
Sodium thiosulphate	Cyanide	A
Succimer (DMSA) 2.3 Dimercaprol succinic acid	Lead Mercury (inorganic and organic) Arsenic	B B B
Tolonium Chloride (Toluidine Blue)	Methaemoglobinaemia	A
Trientine (Triethylene tetramine)	Copper	B
Unitiol (DMPS) 2.3 Dimercapto-1- propanesulphonic acid	Mercury (methyl- and inorganic) Lead	B B

B. AGENTS TO PREVENT ABSORPTION OF TOXIC SUBSTANCES IN THE GASTROINTESTINAL TRACT

ANTIDOTE	MAIN INDICATIONS	AVAILABILITY IN TERMS OF URGENCY OF USE IN TREATMENT
Activated charcoal	(for most poisonings)	A
Cholestyramine	Digitalis, Coumarin Chlordecone	B
Fullers Earth	Paraquat, Diquat	A
Potassium ferrocyanide	Copper	A
Sodium bicarbonate	Iron	A
Sodium sulphate	Organophosphates	A
Starch	Barium Iodine	A

C. AGENTS TO PREVENT ABSORPTION AND/OR DAMAGE ON THE SKIN

ANTIDOTE	MAIN INDICATIONS	AVAILABILITY IN TERMS OF URGENCY OF USE IN TREATMENT
Calcium gluconate gel	Hydrofluoric acid	A
Macrogol 400 (PEG)	Phenol	A
Copper sulphate, sodium bicarbonate, hydroxy-ethylcellulose	White Phosphorus	A

D. EMETICS

ANTIDOTE	MAIN INDICATIONS	AVAILABILITY IN TERMS OF URGENCY OF USE IN TREATMENT
Apomorphine		A
Ipecacuanha		A

E. CATHARTICS AND SOLUTIONS USED FOR WHOLE GUT LAVAGE

ANTIDOTE	MAIN INDICATIONS	AVAILABILITY IN TERMS OF URGENCY OF USE IN TREATMENT
Magnesium citrate		B
Magnesium sulphate		B
Mannitol		B
Sodium sulphate		B
Sorbitol		B
Whole gut lavage fluids (Polyethylene glycol electrolyte (lavage solution		B

F. AGENTS TO MODIFY URINARY pH

ANTIDOTE	MAIN INDICATIONS	AVAILABILITY IN TERMS OF URGENCY OF USE IN TREATMENT
Ammonium chloride		B
Arginine hydrochloride		B
Hydrochloric acid (0.1 N)		B
Sodium bicarbonate		A

FINANCIAL RECORD SHEET

1. Budget items concerned

A 2511: Meetings of committees whose consultation is not compulsory

B 6475: Toxicology action programme

2. Legal bases

- a) The Treaties of the European Communities.
- b) Resolution of the Council and the representatives of the Governments of the Member States, meeting within the Council of 29 May 1986, on a programme of action of the European Communities on toxicology for health protection (OJ No C 184 of 23.7.1986, p.1).

3. Proposed classification into compulsory/non-compulsory expenditure

Non-compulsory.

4. Description and justification of the action

4.1 Description

The Resolution on improving the prevention and treatment of acute poisoning is intended to meet three objectives:

- proposing common forms for the various poison centres in the Community with a view to improving the comparability and use of the clinical data collected;
- facilitating the collection of clinical toxicology data, which is an essential prerequisite for a full evaluation of health risks. The reliability of the information extrapolated from animal data to humans requires further study;
- improving the availability of antidotes within the Community by increasing knowledge on their indications and by providing an incentive for their distribution.

4.2 Justification

The action is justified by the legal bases given in point 2. The financial implications will be associated with the measures set out in point 5.

5. Nature of the expenditure and method of calculation

5.1 Nature of the additional activities to be undertaken following the adoption of the Resolution

- a) Monitoring the implementation of the Resolution in the individual Member States;
- b) consultation with experts;
- c) consultation of the Scientific Advisory Committee set up to examine the toxicity and ecotoxicity of chemical compounds;
- d) computerization of data.

5.2 Types of activity resulting from 5.1 with financial implications

These are:

- Study and/or service contracts undertaken in order to:
 - . compare and evaluate the information received by the Commission
 - . study the problems associated with the practical implementation and effectiveness of the Resolution
 - . computerize the information collected
- Costs of consultation meetings with experts.
- Operating expenses of the Scientific Advisory Committee set up to examine the toxicity and ecotoxicity of chemical compounds, consisting of 12 non-Government experts meeting three times per year.

5.3 Calculation of expenditure

Although only the nature and type of the additional activities are known, with no indication of their scale, it should be possible to keep actual expenditure within the limits set out in 6 below.

The cost of convening a non-Government expert is estimated at 625 ECU.

Costs are calculated on the basis of the "man/month" unit; at present, one unit is equivalent to 5 000 ECU.

The expenditure will be spread over several years and will be progressive. The figures given in 6.1 are approximate estimates.

6. Financial impact of the action on intervention appropriations

6.1 Schedule of commitment appropriations and payment appropriations

Item A 2511

	CA (ECU)	PA (ECU)
1989	25 000	25 000
1990	25 000	25 000
1991	25 000	25 000
1992	25 000	25 000
1993	<u>25 000</u>	<u>25 000</u>
Total	125 000	125 000

Item B 6475

	CA (ECU)	PA (ECU)
1989	50 000	50 000
1990	50 000	50 000
1991	100 000	100 000
1992	100 000	100 000
1993	<u>100 000</u>	<u>100 000</u>
Total	400 000	400 000

6.2 For the work provided for in the Draft Resolution, the Commission will provide 100% funding

7. Remarks

None.

8. Financial impact on staff appropriations

8.1 Personnel needed solely for the action itself

As from 1990, one half-time A official, one half-time B official and one half-time C official will be needed.

The allocation of these resources will depend on the posts and appropriations authorized in the budget and on the scope for redeployment of posts and staff mobility.

8.2 Appropriations needed for staff

The estimated appropriations needed as from 1990 are 120 000 ECU per year.

ASSESSMENT OF IMPACT
ON COMPETITIVENESS AND EMPLOYMENT

Draft Council Resolution on improving the prevention and treatment of acute poisoning.

1. The main aim of the Draft Council Resolution is to harmonize the call data forms and the annual reports and to facilitate the distribution of antidotes so as to provide an incentive at Community level for the poison centres to work together to improve the services they provide to users and to prevent acute poisoning more effectively.
2. The Draft Council Resolution applies to all poison centres in the Community.
3. The measures to be taken by the poison centres in applying this Resolution will entail adapting and harmonizing existing measures, and therefore should not lead to any major financial constraints on public service bodies, which operate outside the sphere of economic competition.
4. The measures taken by the Member States to facilitate the distribution of antidotes should eventually lead to a reduction in their costs.

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