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COUNCIL DIRECTIVE 77/312/EEC OF 29 MARCH 1977 ON BIOLOGICAL SCREENING OF THE POPULATION FOR LEAD

PROGRESS REPORT ON THE IMPLEMENTATION OF THE DIRECTIVE

(Report from the Commission to the Council)

Com 88

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SUMMARY

The Council Directive of 29 March 1977 on biological screening of the population for lead provides that Member States shall assess the extent of exposure to lead outside the workplace. It sets reference levels in terms of blood lead concentrations; where these are exceeded Member States have to determine the source of exposure and take action to eliminate the risk to health.

The Directive provides that the Commission, in cooperation with the Member States, shall draw up reports on the measures taken to implement the Directive. This report, submitted in accordance with Article 11 of Council Directive (77/312/EEC) of 29 March 1977 JO L105/10.1977 describes the work carried out by the Member States and the Commission in application of the Directive.

In order to ensure a uniform application of the Directive in Member States and a comparable quality of the results, the Commission with the Competent National Authorities nominated by the Member States worked out a standardized "Subject Questionnaire and Data Sheet" and an "Information Notice to General Practitioners", and at the same time initiated a Quality Assurance Programme for blood lead analyses with the participation of more than 50 laboratories from all the Member States. This Quality Assurance Programme having allowed for considerable improvement in the quality of blood lead analyses has become a well established Programme which continues at the request of the Competent National Authorities and the participating laboratories.

Together with the Competent National Authorities practical criteria were established for the selection of the population groups for screening both in urban areas and in areas with specific sources of lead.

A total of close to 18,000 subjects, evenly distributed between women and men, has been examined throughout the European Community. A significant percentage of the subjects involved were children. 168 separate areas and population groups have been investigated.

The median blood lead level for the selected population in the Community is of 13µg lead/100ml blood. Just over 2% of the subjects examined exceed 30µg and 1.05% (or 184 subjects) exceed 35µg. It must be recalled that a median value below 20µg is considered acceptable by the Directive and that individuals with blood lead levels in excess of 35µg are to be further evaluated. There are significant differences in blood lead levels in the different study areas. However, in general the levels are lower than could have been anticipated from earlier fragmentary studies.

The studies conducted in the large urban areas seem to indicate that there is no special lead health risk for the population if there are no specific sources of lead such as point emission sources from industry or plumbosolvency.

The studies conducted in potential problem areas have confirmed that in a number of instances the reference levels are exceeded and that therefore a health risk may exist. Member States are currently taking active measures to better define the problem and take remedial action where necessary. The second screening campaign foreseen by the Directive and now in the planning stage will place special emphasis on such types of areas.

1. INTRODUCTION

The Council Directive on biological screening of the population for lead is aimed at assessing the non-occupational exposure of the population to lead in the Member States of the Community, and where necessary to eliminating the causes of high exposure.

The exposure is to be determined through a biological screening of the population, and is to be assessed by comparing it with reference levels laid down in the Directive (blood lead limits for the population as a group as well as for individuals).

The Directive provides that the Commission, in cooperation with the Competent National Authorities shall prepare periodic reports on the measures taken to implement this Directive. The present report is the first such report.

For the uniform implementation of the Directive a number of formal meetings of the Competent National Authorities as well as Ad-hoc working groups were held (Annex 1 - list of meetings and membership) and several reference documents prepared (Annex 2 - Subject Questionnaire and Data Sheet, Annex 3 - Information Notice to General Practitioners).

2. THE MAIN PROVISIONS OF THE DIRECTIVE

The Member States are required to take the necessary steps to promote the screening procedure according to the following conditions:

- the application of the Directive to be restricted to 4 years (Article 2);
- the procedure is based on the measurement of blood lead with or without ALAD levels (Article 2);

with the further stipulations that:

- the sampling be carried out on volunteers (Article 3);
- there shall be groups of at least 100 persons examined in urban areas of more than 500,000 inhabitants (Article 4, indent 1);
- groups of at least 100 persons shall be chosen where feasible from among people exposed to significant pollution (Article 4, indent 2);
- other critical groups shall be examined as determined by the Member States (Article 4, indent 3);
- in each Member State and during each campaign the number of analyses to be performed shall be 50 or more per million inhabitants (Article 4).

The campaign is to be carried out in two stages separated by at least 24 months (Article 5).

Reference levels are specified which take into account dose and effect. These reference levels (Article 6) are:

- a maximum of 20µg lead/100ml blood for 50% of the people examined;
- a maximum of 30µg lead/100ml blood for 90% of the people examined;
- a maximum of 35µg lead/100ml blood for 98% of the people examined.

In order that the results of the blood lead analyses during the campaign shall be as accurate and comparable as possible, intercomparison (quality control) programmes shall be carried out in which the nominated laboratories of the Member States shall participate (Article 7).

Member States are required, in the event of the reference levels being exceeded and in the case of individuals with PbB values in excess of 35µg to check the validity of the results and to trace the source of exposure responsible for such overexposure and, further, to take such subsequent action as may be necessary. Such action is to be reported to the Commission.

3. IMPLEMENTATION OF THE DIRECTIVE AT COMMUNITY LEVEL

Following the nomination by Member States of the Competent National Authorities (CNA) a first meeting of these authorities was held in December 1977. To date five formal meetings of the CNA were convened. Ad-hoc working groups have been active on the:

- development of a Common questionnaire to be administered during the campaign;
- production of an information notice for general practitioners;
- monitoring of the Quality Control programme;
- statistical presentation and evaluation of the results.

A Quality Control Programme for blood lead analysis was started in May 1978.

4. IMPLEMENTATION OF THE DIRECTIVE IN MEMBER STATES

Whilst the Directive in Article 4, with three indents, outlined those areas in which monitoring should be conducted, it was nevertheless the task of the individual Member States themselves to determine the actual locations and the manner in which it is most practicable to select representative populations.

4.1 In the matter of large cities (Article 4, indent 1) having a population of greater than 0.5M inhabitants it was judged important to break this into two components - an Inner and an Outer (suburban) zone. This offered the possibility of using the suburban population as a comparison group against the Inner zone.

4.2 Selection of persons presents some problems which are dependent on local (national) organization.

In order to locate suitable populations within the meaning of Article 4, indent 1, many Member States have made use either of National Registers of population or the more detailed local (city) Electoral lists.

Valuable earlier studies performed in Ireland, Belgium, the Federal Republic of Germany, the United Kingdom, Italy and France have shown that in order to obtain a defined number of people, say 100, it is necessary to prepare lists - by random selection from Electoral lists - of 200-300 since the positive response to invitation only may not exceed 30-40% of those persons who have been approached. It is worth noting that a better response can be expected where there is public awareness of a local hazard.

4.3 Electoral lists are necessarily restricted to voting age in each country. There is an age gap between the very young children - who are considered to be a "critical group" (Article 4, indent 3) - and the adolescent group below voting age. The programmes of most National Authorities have paid particular attention to the younger group - the Federal Republic of Germany has, for example, shown particular interest in the 7-12 year age group, as well as the Netherlands with 74% child component and approximately half of the total programme from the United Kingdom is concerned with children. Although national programmes are variable most show a child component of at least 30-50% of the total population being screened.

4.4 Having defined an appropriate population for inclusion in the screening programme it was deemed convenient by some National Authorities to make use of health centres, or some other central premises, where the sampled subjects could be investigated. However a risk of bias can arise by such an arrangement. This bias should be compared with that arising from the selection factors mentioned in 4.2 above.

The Member States having selected Health Centres or Blood Transfusion Centres for the study have done so only after a preliminary investigation.

4.5 Indent 2 of Article 4 invited Member States to submit data for "exposed groups" of their own choice. Arrangements have been made in some Member States to study populations:

- in zones of high traffic density to study the effects of lead emission from petrol;
- at sites adjacent to industrial enterprises where lead is worked or with which lead is associated (smelters, mines, battery works, etc.);
- in areas with high content of lead in drinking water.

Another area which has attracted some Member States in accordance with Article 4, indent 3, is the possible hazard to pregnant women.

4.6 The investigation areas and critical groups selected by Member States for this first campaign are summarized in Annex 5 and presented on maps 1 to 4.

4.7 In order to assist in depth study at individual level vis-à-vis the results of blood lead analyses a questionnaire was devised in consultation with Member States. The questionnaire provided for the collection of data on the following aspects:

- Identification of subject (confidential to local survey organization or National Authorities)
- Identification of Member State, Area and Type of Survey.
- Identification of age, sex, years of residence at present address.
- Information whether or not residence was constructed before 1945.
- Identification of occupation to exclude lead exposure.
- Information on personal habits : smoking and drinking (including water).
- Details of blood analysis including result, where analysed and on what date together with evidence of quality control of primary analysis.

The form also contained facility for recording details of follow up procedure in the event of a blood lead level being found which transgressed the reference levels. A list of 20 occupations associated with lead exposure was appended to assist interviewing personnel.

A specimen of the Questionnaire is appended in Annex 2.

4.8 Collection of blood samples. Regarding the blood sample collection it was necessary to ensure non-contamination. Previous experience and pilot studies had emphasised the need for checking specimen containers and collecting blood samples in such a way that no contamination could occur. Each Member State had examined these possibilities very thoroughly, instituting, where necessary, training courses for personnel engaged in the collection of blood samples. Most had anticipated the possibility of chemical contamination of containers and have arranged to carry out prior studies to ensure that this does not occur.

4.9 Laboratory support. Thirty three laboratories carried out the blood lead analyses required. For the selection by the CNA of the laboratories which were to carry out the analyses, each laboratory has been required to participate in a series of tests of performance (Quality Control - QC) operated by the Commission. Additionally each laboratory was required to participate in further intensive Quality Control programmes (QCP) which were carried out whilst the screening exercise was conducted (see Annex 4).

5. RESULTS OF THE FIRST CAMPAIGN

5.1 Validation of Assays of Blood Lead

The importance of obtaining the best possible results for the blood lead assays during the biological monitoring exercise had been stressed at all times. The Competent National Authorities nominated laboratories based upon the results of the QCPs, and maintained vigilance of the results of QC performance during the monitoring exercise proper.

It was realised from the inception of the programme that contamination must be avoided, both during the taking of samples of blood and from any containers into which the blood was introduced. Only trained operators were used to collect blood samples, and each country undertook a "pre-analytical" QC exercise of the blood container tubes to exclude the possibility of contamination from that source.

The arrangements for duplicate analysis of samples, especially of those where primary analysis revealed levels in excess of 35µg/l, and where second sampling was important, were in the hands of the National Authorities. Additionally some Member States arranged to submit a proportion of blood samples for analysis "blind" to the Joint Research Centre of the CEC at Ispra.

Table 1 appended summarizes all the arrangements made for the validation of assays of blood lead.

5.1.1 Analysis of samples by CEC Reference Laboratory
(Joint Research Centre at Ispra)

Six Member States submitted samples for secondary analysis to Ispra. A total of 1298 samples were examined during the period September 1979 to February 1980 excepting for the samples from Luxembourg which were examined in May 1979.

The Ispra laboratory employed 3 different methods of analysis, most of the samples in which 2 supplementary methods were used were those with a blood lead level greater than 20µg/dl.

Results of analysis by the original laboratories and the reference laboratory have been grouped by survey, and correlation coefficients have been calculated.

For the most part the order of agreement between the results from the Ispra laboratory and the laboratories performing the primary analyses was good. The maximal grouped deviation was +3µg/dl. The majority of the comparative group deviations lie between -0.3 and +2.0µg/dl.

More than 95% of the results analysed in duplicate were within less than 4µg/100ml PbB of each other, giving a clear indication of the reliability of the results obtained.

5.2 Summary of the numerical results

A summary of the number of subjects examined in each Member State and the number of areas studied is given in Table 2. The distribution of the subjects in terms of types of areas and study is given in Table 3.

A summary of the results obtained in each of the 168 individual surveys carried out to complete the first measurement campaign in compliance with the Directive is given in Annex 5. This summary contains for each of the surveys an indication of the number of subjects examined and the blood lead results in terms of 50, 90 and 98 percentile.

For most of the areas examined and types of studies undertaken the blood lead levels found do not exceed the three reference levels provided in the Directive. An overall assessment of the results is given in Table 4.

For the adult population, with five apparent exceptions, the blood lead levels of the adult population living in all areas without specific lead sources are below the reference levels. The median values found in the studies for these populations varied from 6 to 19µg/dl with an overall median of 13µg/dl.

An assessment of the results in terms of potentially exposed groups and "critical" groups is given in Table 5.

An analysis of the results based on sex confirms that, in general, the blood lead levels of women are a few micrograms/dl lower than in men.

An in depth study taking into account the additional information derived from the Questionnaire is being made and a special Technical Report is being prepared.

6. FOLLOW-UP ACTION

The Directive foresees in Article 8 that if blood lead results exceed the reference values the validity of the data must be checked, sources of exposure must be searched for and measures taken at National discretion. A description of the actions taken to date and communicated to the Commission as laid down in Article 9 is given below for each of the Member States.

6.1 Belgium

Practically all the areas investigated produced blood lead levels (PbB) below the reference levels of the Directive. However, in a number of instances the levels came very close to these values.

Two areas deserve special mention, the Antwerp Industrial Basin and Verviers. Both areas were known to have a potential lead problem, the first one due to a lead smelter and the second due to plumbosolvency.

The results for the Antwerp Industrial Basin (median 17, 90-percentile 26 and 98-percentile 32) for adults are not unexpected in spite of the presence of a large lead smelter. Previous studies have shown that the effect of the pollution by this smelter is limited to a radius of 2Km and affects mainly children. Since 1974 critical groups of children are monitored regularly. Strict emission standards have been set and technical measures taken to comply with them. At present regular twice yearly screening of children of school and pre-school age is carried out.

The Verviers area (median 24, 90-percentile 39 and 98-percentile 59) is the only one exceeding the reference values. The results are as expected since the plumbosolvency problem has been known for some years. At present the situation is being corrected. Lead pipes are progressively replaced; a special canalisation system for the textile industry to distribute soft water is being installed, thus allowing for the treatment of the water distributed to the population.

Shortly PbB measurements will be carried out on school age children in the area.

6.2 Denmark

In general PbB levels in Denmark were found to be well below the reference levels of the Directive.

It was found however that a group of children whose fathers worked in a lead manufacturing enterprise had significantly higher PbB values compared with other groups of children, even if still below the reference levels. In order to be on the safe side the Directorate of Labour Inspection Service after having examined the enterprise has enjoined that the common hygiene measures be tightened (for example no smoking or eating in the factory, complete separation of private and work clothes, and bathing at the end of the work day).

The children's survey has increased the attention of the Directorate of Labour Inspection Service at other lead factories where they have also enjoined measures of hygiene.

The surveys of the adult population did not show any significant sources of lead in the general population and have not inspired any specific measures against lead pollution.

6.3 Federal Republic of Germany

Follow up action and studies were undertaken in particular in two areas where the 35µg/100ml PbB reference value was exceeded: Rheinland Pfalz and Niedersachsen, from a battery works and a lead smelter respectively.

Immediate individual measures were taken for the children with the highest PbB values. They were sent for medical check-up to a health centre: no manifest symptoms of lead intoxication were noticed.

Up to now the following additional measures and steps have and are being taken:

In Rheinland Pfalz a group of 17 children with high lead exposure (also under 35µg/100ml PbB) are being sent on a State-paid vacation in a resort area for 4-5 weeks to reduce total individual exposure.

In Niedersachsen, based on the results of the campaign, the "Land" government initiated a situation analysis.

In order to follow the recommendation of the Directive to focus special attention on children of lead workers, 100 children were selected of which over 60 had parents occupationally exposed to lead in the first phase (November 1979). All children live in the direct proximity of the lead plant. The results of the PbB study showed that all the reference values of the Directive were clearly exceeded. 24% of the children had PbB levels of over 35µg/100ml.

In March 1980 (Phase 2) the study was repeated with 248 persons, this time including adults. 28 children participating in March had also been in the November group.

The findings of this phase indicate a strong seasonal influence on the PbB level. The March levels were 28% lower than in November; these PbB levels were corroborated by FEP levels which were also determined, and showed a 21% decrease.

Beginning in April 1980 (phase 3) an extensive screening programme of persons living in the area was initiated. Until now over 1500 volunteers (adults and children) have participated. Besides specific parameters for heavy metal exposure (such as Pb-hair, PbB, Cd-hair) the general health status of all persons was studied by means of a mobile unit of the Bundesgesundheitsamt (Federal Health Office). Evaluation is still in progress.

6.4 France

For the moment the blood lead surveillance campaign has been carried out essentially in large urban areas on adult populations. In several instances however critical groups such as pregnant women were examined (Paris and Toulouse). The results were in general significantly below the reference levels set out in the Directive.

The surveillance of the population living in the vicinity of industrial complexes with lead emissions is currently being undertaken. This surveillance implies a close collaboration with the local authorities, and may lead as a function of the results to the application of preventive measures appropriate to the importance of the risk. The industrial activities concerned are primary and secondary lead smelters, battery manufacturing plants and tetraethyl production units. Areas where there is a danger of lead exposure due to plumbosolvency will also be examined.

At present a first selection of the areas has been made as well as an inventory of the sources of lead pollution.

6.5 Ireland

The results of the population survey carried out in Ireland which included both urban areas and critical groups (children near a lead source) show that there is no general or specific lead problem in Ireland. 80% of all PbB results were below 15µg/100ml.

With respect to the reference levels set out in the Directive 94,2% of the population sampled has PbB below 20µg/100ml, 99.6% below 30µg/100ml and 100% below 35µg/100ml.

6.6 Italy

The Biological screening campaign in Italy has covered both urban areas and areas with point or significant sources of lead (Murano, Sassuolo, Paderno).

In general it may be said that the PbB while significant, only seldom exceeds the reference levels laid down in the Directive.

In the critical areas where the levels have been exceeded the local health authorities in agreement with the trade unions have continued the control of the industrial establishments in order to ascertain:

- the application in the production processes of the appropriate abatement techniques in order to avoid pollution by lead;
- the efficiency of these abatement techniques through lead in air measurements;
- that the appropriate personal hygiene measures are followed by the workers.

With respect to the slight exceeding of the reference levels in two urban areas (Bologna and Turin), the national authorities will consider the appropriate measures to take, in particular the determination of the origin of these high levels, if the second screening campaign confirms the results of the first.

6.7 Luxembourg

During the sampling campaign, applying the strict interpretation of the Directive, no person with PbB levels above 35µg/100ml was found. However a print shop worker with a PbB level of 60 was found (professionally exposed but not followed medically for such exposure).

In collaboration with the Public Health Inspection and in agreement with the management of the print shop, an overall monitoring of all the volunteer workers in the shop was carried out (PbB, ALAD, ALAU, basophilic stipple cells). Four workers were found to have a high body burden of lead.

On the basis of hygiene recommendations, and improvements in the printing operations the situation was improved as was shown by subsequent PbB monitoring.

Even without the discovery of "hot spots" in Luxembourg, this surveillance of the population has resulted in an increased awareness of the public health authorities and the population for the problems which may be produced by lead.

6.8 Netherlands

In application of the screening of the population programme foreseen by the Directive mainly 4 to 7 year old children have been studied. The various subgroups showed marked differences: the children living in inner urban areas had the highest blood lead levels. Nevertheless all the groups of children were significantly below the reference levels laid down in the Directive.

In one male adult group from Amsterdam the 98-percentile just exceeded 35µg/100ml: the median and the 90-percentile, however, did meet the terms of the directive. Follow-up investigation has been done of the three men having blood lead levels of over 35µg/100ml. Interestingly, two of these men appeared to be painters in an urban renewal project, the third one could not be contacted.

6.9 United Kingdom

In the United Kingdom four population groups were found whose blood lead concentrations exceeded the reference levels.

In Glasgow the results for adults exceeded the 35µg/100ml reference but by a small margin. The existence of a lead in water problem there is well-known and the water authority for the area has introduced lime-dosing of almost all of the city's water supplies; the lime-dosing was enhanced in 1980.

The 35µg/100ml level was marginally exceeded at Leeds for a group of lead workers' children. The cause is thought to be insufficient use of washing and other facilities by workers preparing to go home. The company and the relevant pollution control authorities are paying particular attention to workers' hygiene.

At Chester the distribution of blood lead levels of both lead workers' children and children living near the lead works exceeded the upper reference level. For the former group, workers' poor hygiene is the source of enhanced exposure, while the residents have most probably been exposed to dust blown at low level from within the works. The company has tightened up on workers' hygiene and has undertaken an investment programme including measures for improved pollution control.

The national pollution control authorities are advising the company while the local authority has increased its efforts to monitor air and dust lead levels around the works, particularly near schools. In all cases where individual blood lead concentrations exceeded 35µg/100ml the local authorties have investigated their homes and advised parents on removing specific sources of exposure to lead.

The results for all the other investigated areas were all well within the reference levels laid down in the Directive.

7. PRELIMINARY CONCLUSIONS

The overall campaign has been monitored by a very comprehensive quality assurance programme lending confidence to the interpretation of results.

In general blood lead levels for the population of the Community were lower than could have been anticipated from earlier fragmentary studies.

The studies conducted in urban areas with no known specific sources of lead (point emission sources from industry, plumbosolvency and lead pipes) seem to indicate that there is no special risk for the population taking into account the reference values provided for in the Directive.

Studies conducted in areas with known specific sources and in particular for critical population groups such as children of lead workers or children living near lead works, have confirmed that a health risk may exist since in some of those instances reference levels have been exceeded. This has been the case for known problem areas and for newly found potential problem areas.

Member States are taking active measures to better circumscribe the problem and taken remedial action where necessary.

In view of this situation in the second campaign special emphasis will be placed on such types of areas.

TABLE 1

Validation of Assays of Blood Lead Analyses

Validation steps \ Member State	B	DK	F	D	IRL	I	L	NL	UK
1. CEC Quality Control	+	+	+	+	+	+	+	+	+
2. Internal Pre-analytical QC	+	+	+	+	-	+	+	+	+
3. Confirmation of results by 2nd laboratory	+	(10%)	+	(10%)	-	(30%)	+	-	(10%)
4. Duplicate check at 35µg/dl	+	⊘	+	+	⊘	+	⊘	+	+
5. Duplicate check at 30µg/dl		-	+					+	+
6. % of total samples submitted to CEC reference laboratory (Ispra)	8%	0%	0%	14%	10%	11%	15%	0%	2%

(1, 2, 3, 4, 5) + means that this Member State has performed this step.
- means that this Member State has not performed this step.

(3) The figures in brackets correspond to the percentage of samples sent to the second laboratory.

(4) ⊘ means that no results >35µg/dl were found.

TABLE 2. POPULATION EXAMINED IN THE EUROPEAN COMMUNITY

Country	Nb.of areas/ type of survey	Number of subjects	male	female
BELGIUM	14	1678	1026	652
DENMARK	6	377	185	192
F.R. GERMANY	68*	5437	2682	2755
FRANCE	10	1802	782	1020
IRELAND	5	240	106	134
ITALY	12	2512	1099	1413
LUXEMBOURG	3	165	74	91
NETHERLANDS	13	767	369	398
UNITED KINGDOM	37	4631	2350	2265
E.C.	168	17609	8673	8920

* with more than 20 subjects

TABLE 3: DISTRIBUTION OF SUBJECTS IN TERMS OF AREA AND STUDY TYPES

		number of subjects	
I. Distribution by areas			
inner urban	> 0.5 M	~ 5300	addr sses of 700 subjects unknown
outer urban	> 0.5 M	~ 3300	
inner urban	< 0.5 M	~ 1700	
outer urban	< 0.5 M	~ 2800	
rural		~ 2000	
II. Distribution by main source			
lead works in environment		~ 3100	
lead workers (relatives)		~ 1700	
lead pipes		~ 900	
busy roads		~ 2800	
naturally high Pb level		~ 65	
III. Distribution by population group			
children		~ 5800	
pregnant women		~ 100	
adults		~ 11700	

TABLE 4

OVERALL ASSESSMENT OF THE BLOOD LEAD

RESULTS FOR THE EUROPEAN COMMUNITY

Total nb. of subjects	Nb. of subjects with blood lead level > 30 µg/dl	Nb. of subjects with blood lead level > 35 µg/dl	Median for Community
17609	367 (2%)	184 (1%)	13 µg/dl

TABLE 5

ASSESSMENT OF THE RESULTS IN TERMS OF
OF POTENTIALLY EXPOSED GROUPS AND "AT RISK" GROUPS

subjects	50 percentile		90 percentile		98 percentile	
	range µg/dl	median µg/dl	range µg/dl	median µg/dl	range µg/dl	median µg/dl
children (no source)	6–16	10.5	9–25	13.9	11–42.8	16
children (with source)	7–20	14	12–32	21	15–56.6	25.4
adults (with source)	7–24	13	11–39	20	17.9–59	26.9

ANNEX 1.

LIST OF MEETINGS HELD CONCERNING EEC DIRECTIVE 77/312/EEC

	1977
(1) 1st Meeting of Competent National Authorities	5/6 December
	1978
(2) Ad hoc Working Group of Representatives of Competent National Authorities-concerning Quality Control.	30/31 January
(3) Ad hoc Working Group of Representatives of Competent National Authorities-concerning implementation of Directive.	31 January-1 February
(4) Working Party on Quality Control.	18 May
(5) Working Party concerning the Questionnaire.	20 July
(6) Meeting of Working Party concerning preparation of Quality Control materials.	11/12 October
(7) Meeting of Working Party concerning the Information Notice for General Practitioners.	12/13 October
(8) 2nd Meeting of Competent National Authorities.	17/18 October
(9) Meeting of Working Party concerning the Questionnaire.	5/6 December
	1979
(10) 3rd Meeting of Competent National Authorities.	22/23 March
(11) Meeting of Working Party concerning Statistics.	19 April
	1980
(12) Meeting of Working Parties on Quality Control and Statistics.	24/25 April
(13) 4th Meeting of Competent National Authorities	24/25 June

ANNEX 1 A.

LIST OF NATIONAL CO-ORDINATORS

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ANNEX 1 B

LIST OF PARTICIPANTS TO THE MEETINGS

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R. Lauwerys	(1)
M. Legrand	(9)

BUNDESREPUBLIK DEUTSCHLAND

A. Brockhaus	(1)
Brunsweig	(12)
N. Englert	(1-3-5-7-9-10)
K. Holl	(8-12-13)
G. Kallischnigg	(11)
C. Krause	(2-10)
Mutteltssen	(12)
K.H. Schaller	(6-10)
E. Schmidt	(9-10-11-12-13)
W. Schulz	(13)
G. Terbeck	(1)
R. Turck	(12)
M. Wagner	(1-3-4-8-11-12-13)

DANMARK

K. Grunnet	(9)
J. Hansen	(1-3-10-11-12-13)
A.o. Jensen	(10-13)
G. Ketting	(13)
E. Magid	(2-3-4-6)
E. Nielsen	(1-4)
O. Olsen	(1-8)

FRANCE

C. Boudène	(1-2-3-4-7-9-10-12-13)
M. Jouan	(1-3-8-10-11-13)
P. Lazar	(8-10-11-13)

IRELAND

J. Cronin	(1-8-10)
D. Feeley	(1-2-4)
H. Grimmes	(2-3-5-10)
F. Hill	(1)
J. Humphreys	(1-3-8-9-10-13)
B. O' Donnell	(10)
D. Page	(1)
P. Power	(10)
S. Trant	(12)

ITALIA

L. Alessio	(3-7)
L. Binetti	(13)
A. Bortoli	(1-2-5-10-13)
M. Buratti	(10)
S. Cerquiglini	(1-8-10)
G. Matiello	(1-2-5-6-9-10-12-13)
G. Morisi	(8-10-12-13)
A. Stacchini	(4)
T. Taggi	(3-9-11-12-13)
G. Vivoli	(10)

LUXEMBOURG

G. Hansen	(8-9-10-11-13)
J.P. Hoffmann	(1-4-8)
P.H. Huberty-Krau	(10)

NEDERLAND

G. Ellen	(12)
C.M. Huisman	(1-3-8-11-13)
A. Ligeon	(10-11-12)
J.J.L. Pieters	(8-10)
P.L. Schuller	(2-4-6-13)

UNITED KINGDOM

A. Archer	(10-13)
A.D. Bostock	(10)
G. Carter	(10)
H.T. Delves	(1-2-4-6-10-12-13)
J. Facer	(1-3-7-8-10-11)
J.P. Giltrow	(1)
N. Jackson	(13)
E. Lummis	(1-3-8-10)
P. Mac Cornack	(11)
I.B. Millar	(10)
P. Parris	(9-12-13)
F. Reynolds	(10)
P. Tan	(5)

COMMISSION OF THE EUROPEAN COMMUNITIES

R. Amavis	(1-2-3)
A. Berlin (Chairman)	(1-2-3-4-5-6-7-8-9-10-11-12-13)
A. Bonini (Secretary)	(1-2-3-4-5-6-7-8-9-10)
E. di Ferrante	(1-3)
M. Langevin (Assistant)	(1-2-3-4-5-6-7-8-9-10-12-13)
W. Leyendecker	(1-2-4-6-8-9-10-12-13)
J. Pickford	(1-4)
B. Yeoman (General rapporteur)	(2-4-6-7-8-9-10-12-13)

COMMISSION
OF THE
EUROPEAN COMMUNITIES

Directorate-General
Employment and Social Affairs

Health and Safety
Directorate

V/F/1

ANNEX 2

SUBJECT QUESTIONNAIRE AND DATA SHEET

FOR THE IMPLEMENTATION OF COUNCIL DIRECTIVE OF 29 MARCH 1977

ON BIOLOGICAL SCREENING OF THE POPULATION FOR LEAD

(77/312/EEC)

Identification number

2.1	2.2	2.3	2.4

PART 1 - PERSONAL INFORMATION

(confidential)

1.1 Requested information:

1.1.1 Personal number of subject .....
1.1.2 Date questionnaire completed .....
1.1.3 Surname .....
1.1.4 First name .....
1.1.5 Residential address .....
1.1.6 Postal code .....
1.1.7 If possible:
home telephone number .....
workplace telephone number .....

1.2 Transmission of results:

no

yes — to the subject
to the general practitioner

only if elevated Pb-B — to the subject
to the general practitioner

1.3 General practitioner:

Name .....
Address .....

1.4 Type of work	Present	Previous
1.4.1 Type of work	.....	.....
1.4.2 Type of industry or economic activity	.....	.....
1.4.3 Number of years in the occupation in the industry or economic activity		

Identification number

2.1 2.2 2.3 2.4

Part 2: BACKGROUND DATA

Identification number		For local or national use	For CEC use
2.1 Member State			1,2
2.2 Area Code *			3-6
2.3 Type of Survey *			7-9
2.4 Personal number of subject			10-13
2.5 Date questionnaire completed	day month year		14,15 16,17,18,19
2.6 Sex	Male		20
	Female		21
2.7 Date of birth	month year		22,23 24,25
2.8 Years of residence at present address			26,27
2.9 House built	before 1945 1		
	after 1945 2		28
	unknown 3		

2.10	Present	Previous	Present	Previous	Present	Previous
2.10.1 Occupation (code according to list in annex)					29,30	31,32
2.10.2 Number of years in the occupation corresponding to 2.10.1					33,34	35,36
2.10.3 Medical surveillance for occupational lead exposure	yes no	yes no			37, 39	38. 40

Identification number

2.1	2.2	2.3	2.4

	For local or national use	For CEC use
2.11 Smoking habits		
2.11.1 cigarettes/day		
non smoker or <5 ☐	☐	41
5-20 ☐		42
>20 ☐		43
2.11.2 Pipe / cigar ☐ yes ☐ no	☐	☐ 44 ☐ 45
2.12 Predominant drinking habits*		
Tap water ☐	☐	46
Bottled water ☐	☐	47
Milk ☐	☐	48
Canned juices ☐	☐	49
Beer ☐	☐	50
Wine ☐	☐	51
Spirits ☐	☐	52
2.13 Exposure of other members of Household to occupational lead		
Yes No Unknown		
Spouse 1☐ 2☐ 3☐	☐	53
Father 1☐ 2☐ 3☐	☐	54
Mother 1☐ 2☐ 3☐	☐	55
Other 1☐ 2☐ 3☐	☐	56

* See annex

Identification number

2.1	2.2	2.3	2.4

Part 3: RESULTS OF BLOOD LEAD ANALYSIS

	For local or national use	For CEC use
3.1 Blood Sampling		
3.1.1 Date of collection of blood sample (day month year)		57,58 59,60 61,62
3.1.2 Method of blood sampling		
Capillary: 1 ☐ / Venous: 2 ☐	☐	☐ 63
3.1.2 Anticoagulant		
EDTA 1 ☐ / Heparin 2 ☐ / Citrate 3 ☐ / Other 4 ☐	☐	☐ 64
3.2 Blood Analysis		
3.2.1 Date of Analysis (day month year)		65,66 67,68 69,70
3.2.2 Code number of laboratory		71,72,73
3.2.3 Blood Lead Result (µg/dl)		74,75,76
3.2.4* Results of Internal Quality Control sample on same day (µg/dl) Blue		77,78
Red		79,80

* Only for laboratories using these samples

Identification number

2.1	2.2	2.3	2.4

O P T I O N A L

Part 3: DUPLICATE BLOOD LEAD ANALYSIS (results obtained in systematic national duplicate analysis scheme)

A Duplicate Blood Lead

A.1 Date of Analysis ☐☐ ☐☐ ☐☐ (day month year)

A.2 Code number of laboratory ☐☐☐

A.3 Blood lead result (µg/dl) ☐☐☐

A.4* Results of Internal Quality Control Samples on same day (µg/dl)

Blue ☐☐

Red ☐☐

* Only for laboratories using these samples

Identification number

O P T I O N A L

2.1	2.2	2.3	2.4

Part 3: RESULTS OF BLOOD ANALYSIS - OTHER METALS

B. Cadmium

B.1 Date of Analysis ☐☐ ☐☐ ☐☐ (day month year)

B.2 Code Number of Laboratory ☐☐☐

B.3 Blood Cadmium Result (ng/l) ☐☐☐

B.4* Results of Internal Quality Control samples on the same day (ng/l)

High ☐☐

Low ☐☐

* Only for laboratories using these samples

C. Mercury

C.1 Date of Analysis ☐☐ ☐☐ ☐☐ (day month year)

C.2 Code Number of Laboratory ☐☐☐

C.3 Blood Mercury Result (ng/l) ☐☐☐

C.4* Results of Internal Quality Control samples on the same day (ng/l)

High ☐☐

Low ☐☐

* Only for laboratories using these samples

Identification number

2.1	2.2	2.3	2.4

Part 4: FOLLOW UP

4.1 Immediate action - Repeat blood sampling and analysis when necessary and in particular if blood lead >35µg/dl. (For each analysis use, if possible, the same classification of results as in Part 3).

4.2 Investigate lead sources in the environment.

- 4.2.1 Industries or craftworks
- 4.2.2 Lead pipes for water supply
- 4.2.3 Lead in air
- 4.2.4 Lead in water
- 4.2.5 Lead in soil
- 4.2.6 Lead in dust
- 4.2.7 Others

4.3 Investigate domestic lead sources

- 4.3.1 Water supply (lead pipes)
- 4.3.2 Lead paint
- 4.3.3 Lead-related hobbies of subject and household members
- 4.3.4 Other domestic sources, i.e.
  - plates and dishes
  - canned food
  - home-grown vegetables and fruit
  - dust
  - cosmetics
  - newspapers
  - toys
  - other

4.4 Other members of the same household examined

Surname	First name	Identification number
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....

4.5 Action taken

- 4.5.1 Removal of source
- 4.5.2 Removal from area
- 4.5.3 Advice to change habits
- 4.5.4 Medical attention

List of occupations associated with lead exposure. (This list is intended to cover the majority of, but not all, occupations associated with lead exposure.)

01 Lead mining or mining where lead is an associated impurity.
02 Handling of lead-containing ore.
03 Lead and Zinc Smelting.
04 Battery and Accumulator manufacture, handling and recycling.*
05 Ceramic and pottery industries and crafts, brick and tile industries.
06 Crystal glass industries.
07 Tin and lead crafts.
08 Plastic industries using lead additives.
09 Solder manufacture and handling.
10 Lead printing and inking.
11 Lead paint manufacture and handling.*
12 Demolition work.
13 Shooting Range activities.
14 Lead Ammunition manufacture and handling.
15 Lead Arsenate Spray manufacture and handling.*
16 Manufacture and mixing of organo lead compounds.
17 Garage mechanics.
18 Occupational exposure to lead petrol fumes.*
19 Persons concerned with lead and tin added to car bodies and persons removing lead paint.
20 Lead pigment manufacture.
00 All other occupations (no lead exposure).

* It was felt that the following additional comments might help the questionnaire administrator:

02 Handling of lead ore - this would include those involved in its transport.
04 Battery and accumulator manufacture, handling and recycling - this would include railway workers involved in recharging locomotive accumulators.
11 Lead paint manufacture and handling - this mainly refers to anti-rust paint used in building construction and in car painting. Lead chromate paint is also used by road workers painting yellow lines.
15 Lead arsenate spray manufacture and handling - this is still used as an agricultural spray in some areas.
18 Individuals exposed professionally to lead petrol fumes - this would include petrol attendants at garages, policemen in high density traffic areas, road toll collectors on motorways.

ANNEX

*

2.2 Area code (the list must be provided by the Member States)

2.3 Type of survey ☐☐☐

☐ Type of area

1. Inner urb > 0.5 M
2. Outer urb > 0.5 M
3. Inner urb < 0.5 M
4. Outer urb < 0.5 M
5. Rural

☐ Source

1. No source

Main source

2. lead works in environment
3. lead Workers (relatives)
4. lead pipes
5. busy road
6. naturally high Pb level

☐ Pop.group

1. children
2. preg. women
3. adults
4. others

2.12 Drinking habits

Indicate that a person drinks one or more beverages if the person drinks regularly substantial quantities.

ANNEX 3

Information Notice for General Practitioners

Regarding the Significance for Health of Blood Lead Levels

Model for possible use by Member States

(within the framework of the Council Directive on

Biological Screening of the Population for Lead)

1. INTRODUCTION

Public concern has been increasingly alerted to the possible dangers of lead to health. The response of the Council of the European Communities has been to enact, in 1977, a Directive instituting a biological screening of the general population for lead. The Directive also foresees that action will be taken by Member States in those instances where blood lead levels exceed the reference levels laid down in the Directive (see section 4).

The significance of lead for health cannot be described in simple terms. In an individual case it depends on the nature of the environmental exposure to lead (e.g. whether it is fluctuating or stable, long or short in duration) on sex and age. In the case of a population survey the significance lies in the distribution of the blood lead concentrations in the population, which will be discussed in Section 4.

Population surveys done under the Directive are intended to establish the exposure levels to lead of the general population. Persons occupationally exposed to lead are not included.

This paper relates exclusively to lead and its inorganic compounds.

2. SOURCES AND INTAKE OF ENVIRONMENTAL LEAD

Lead is present in air and dust, water, and canned and fresh food. It may be present in a range of other sources, including paint (e.g. on toys) and printed paper (e.g. wallpaper or printer's ink). Drinking water may be plumbosolvent and so extract lead from water pipes or their jointing materials. Imperfectly fired leadglaze pottery may give up

its lead to food, particularly when the food is acid and in contact with the pot for a long time. Children are known to indulge in various hand-to-mouth activities and may take in lead this way from dust. In cases of pica quite large amounts of lead containing material (e.g. paint chips) may be ingested.

3. METABOLISM OF LEAD

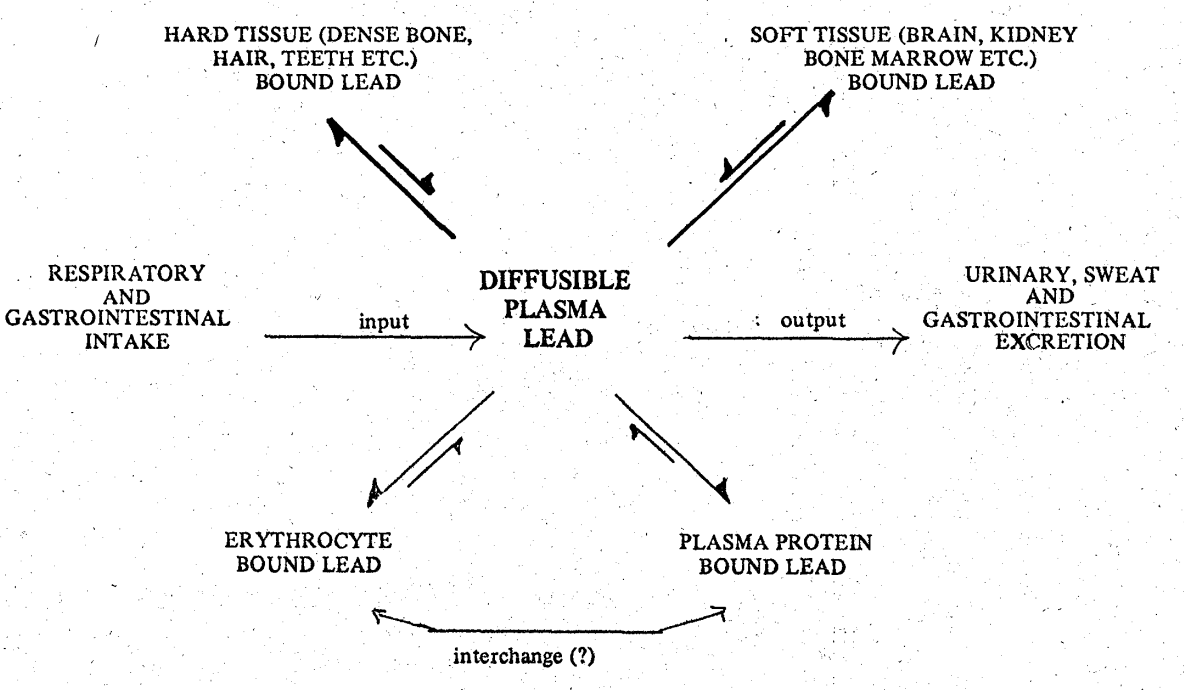
In adults 5-10% of ingested lead is absorbed. The absorption in children is variable, but can be very much higher; up to 50% has been reported. The amount of inhaled lead that is absorbed depends on the size of the particles inhaled. In general the rate is 30-40%, the remainder being either trapped in the upper respiratory passages or exhaled.

Lead passes the placental barrier and enters the foetus. The PbB of the mother is about the same as the lead concentration in cord blood.

Absorbed lead enters the blood, where about 90% is firmly bound to the erythrocytes. Excretion is by the urine and the faeces, but this is usually less than the amount absorbed and lead accumulates in the bone.

Figure 1

Lead Metabolism



The pattern of metabolism is illustrated in the Diagram. The laboratory assessment of diffusible lead in the plasma is impracticable. The half life for the rapid biological exchange pool is 3-4 weeks, but there is a long term biological pool in the bone which represents about 90% of the body burden and which is normally inactive.

4. INDICATORS AND EFFECTS OF EXPOSURE

It is generally accepted that measurement of the blood lead level is the best available indicator of the amount of lead that is currently being absorbed. It is also a good indicator of lead toxicity and correlates well with the signs and symptoms of clinical lead poisoning.

In a stable environment the blood lead can be expected to remain constant. If the environment changes the blood lead will change and become stable again in 2-6 months.

The correlation between blood lead and lead exposure has been extensively studied in the case of air. It is widely agreed that an increment to the air concentration of lead of 1µg/m^3 (for atmospheric concentrations below 5µg/m^3 and for exposures of several months) can be equated with an increment to the blood lead from 1-2µg/100ml. The relationship between dietary intake of lead and blood lead levels is less well established.
Changes in biochemical parameters and effects corresponding to various blood lead levels are summarized in Table 1.

Taking into account these effects and changes in biochemical parameters the Directive set the following reference levels for blood lead:

- a maximum of 20µg/100ml of blood for 50% of the population examined;
- a maximum of 30µg/100ml of blood for 90% of the population examined;
- a maximum of 35µg/100ml of blood for 98% of the population examined.

TABLE 1

Biochemical changes and effects

Blood lead (µg/100ml)	Biochemical changes/Effects	Population affected
< 10	Start of erythrocyte ALAD inhibition.	Adults and children.
15 - 20	Erythrocyte ALAD inhibition not affecting haematopoiesis.	
20 - 35	Start of FEP increases.	Children (20-25) and adults.
35 - 40	ALA increase in urine becomes significant.	All groups
40 - 50	Anaemia may commence.	Children (lower range) and adults.
40 - 50	Tendency to peripheral neuropathy may develop.	Adults.
50 - 60	Start of CP increase.	Children (lower range) and adults.
50 - 70	Minimal brain dysfunction may begin to be observed.	Children (lower range) and adults.
60 - 80	Encephalopathy may begin to occur	Children (lower range) and adults.

Abbreviations: ALAD Aminolaevulinic acid dehydratase
FEP Free erythrocyte protoporphyrin (=PPE)
CP Coproporphyrin

The Directive also set that the sampling will be only from volunteers and is to be carried out on groups of at least 100 persons in urban areas with more than 500,000 inhabitants, in groups as near to 100 as is feasible chosen from exposed populations, and among critical population groups.

Environmental action is required when any of the above levels is exceeded but individual attention is to be paid to all persons exceeding 35µg/100ml of blood.

Other parameters exist to assess exposure (lead in urine, faeces, teeth or hair) and to evaluate early biochemical changes (ALAD, FEP, ZPP). Such parameters may be used, once significant exposure has been ascertained, for a more in-depth assessment of exposure and for determining if such exposure has an effect on that individual.

5. GROUPS SPECIALLY AT RISK

Children, especially of pre-school age, are the most critical group. Their habits make them more likely to ingest the lead in their environment; they absorb and retain more of the ingested lead than adults; less of their body burden of lead is stored in compact bone; their haemapoietic and nervous systems are more sensitive.

Women are more at risk than men as their haemopoietic systems are more sensitive to lead. If a foetus is exposed to lead the extent and effect of the exposure is not fully known. During pregnancy the normal haemodilution may lower the maternal blood lead a fact which should be borne in mind when assessing the blood lead level in pregnancy.

6. AIDE MEMOIRE ON MANAGEMENT

The interpretation of blood lead levels and assessment of early clinical symptoms may require specialized facilities which are usually not within the ambit of general practitioners. The table below (Figure 3) is intended as an aide mémoire to interpretation of blood leads and suggestions on action which should be taken.

Figure 2

GUIDE TO THE INTERPRETATION OF BLOOD LEAD LIMITS

(Non-Occupational Exposure)

Values expressed in µg/100ml of blood

Children (under 15)	Adults	Action
< 35	< 35	None for adults, for children consider repeat analyses for PbB >30.
35 - 50	35-60	If PbB level confirmed, investigate to eliminate source of exposure, continue observation by GP especially for children and refer pregnant women to specialist.
> 50	> 60	Investigate to eliminate source as above, refer children to paediatrician refer adults to specialist.

ANNEX 4

QUALITY CONTROL

A Quality Control Programme (QCP) consisting of sending unknown blood samples to laboratories for analysis was instituted by the Commission in May 1978. A statistical evaluation is made of the results obtained by each laboratory in relation to the performance of the whole group.

The QCP consisted of:

- samples in duplicate, or triplicate, 'blind' to participants, i.e. encoded,
- samples wherein lead has been added to blood so as to assess the ability of a laboratory to recover the added lead,
- samples from a previous QCP so that repeatability of performance can be assessed.

During the run-up to the biological monitoring programme two QCPs are implemented, and a third more intensive campaign was mounted during the monitoring period proper:

Phase '0' - May 1978 - 9 samples to each of 56 participanting laboratories,

Phase '1' - November 1978 to February 1979 - 10 samples in triplicate (mixed and 'blind' to participants) during 3 months = 30 samples to 45 participants,

Phase '2' - June 1979 to August 1979 (during monitoring programme) 30 samples (including duplicates and triplicates), distributed at weekly intervals to 41 participants during the 12 weeks.

All of these samples are designated as External QC samples (EQC).

Additionally, in order to assist laboratories further, Internal QC samples (IQC) were used. The objective of these samples (of which the concentrations were agreed, and on which limits of acceptance were imposed) was to enable 'in-house' assessment of performance at the actual time of blood lead assay.

The total number of EQC and IQC samples distributed to the laboratories was in excess of thirty thousand overall. These were prepared in the Regional Toxicology Laboratory at Dudley Road Hospital in Birmingham, U.K.

Originally 56 laboratories participated in the QCPs. Assessment of performance was made in each Member State by the Competent Natonal Authority. Of the 33 laboratories which were finally retained for the compaign by the National Authorities 11 (33%) obtained more than 90% of results within the acceptable criteria, a total of 16 laboratories (48.5%) obtained more than 80% of acceptable results, and a total of 22 laboratories (66.6%) attained more than 70% of results within the acceptance band.

During the period of the biological monitoring exercise each of the Competent National Authorities undertook an elaborate series of arrangements to ensure check analyses between laboratories (see Section on Validation of Assays) even to the point of further exclusion of some laboratories.

ANNEX 5: SUMMARY OF RESULTS FOR EACH OF THE STUDY AREAS

I. ADULTS, non exposed, living in inner urban area > 0.5 M

(code of survey 113)

zone	nb. of subjects	% of women	Percentile 50	90	98
AMSTERDAM - N.L.	50	0.0	15.0	28.0	42.0
AMSTERDAM - N.L.	50	100.0	10.0	13.0	15.0
Inner BIRMINGHAM-Sparkbrook	97	52.6	15.0	21.0	24.0
" " -Handsworth	99	44.4	13.0	24.0	29.1
BOLOGNA - Italy	86	31.4	19.0	34.9	45.0
BORDEAUX - France	61	63.9	13	23	28
BRUXELLES (urbain) - B	122	38.5	18	25	32
DUBLIN - Ireland	50	50.0	14.0	21.9	27.9
HAMBURG - Germany	33	66.7	12.0	18.0	28.8
HANNOVER - Germany	41	34.1	10.0	15.9	21.9
KØBENHAVEN - Denmark	71	50.7	10.5	16.0	21.0
Inner LEEDS - U.K.	101	45.0	16.0	24.9	33.9
LILLE - France	98	61.2	11	24	39
Inner LIVERPOOL - U.K.	100	57.0	14.0	22.0	29.0
Inner LONDON-Inslington-UK	87	55.2	12.0	17.3	27.3
" " -Lambeth-U.K.	200	52.5	11.5	18.0	25.0
LYON - France	206	53.4	13	22	31
Inner MANCHESTER - U.K.	100	54.0	17.0	24.0	32.0
MARSEILLE - France	269	38.7	14	25	35
MILANO - Italy	394	69.5	14.0	22.0	31.0
NANTES - France	89	77.5	11	21	29
NAPOLI - Italy	198	50.5	17.0	25.0	30.0
NICE - France	97	58.8	11	21	27
PARIS - France	774	54.8	14	24	32
ROMA - Italy	420	42.9	18.0	27.0	35.0
Inner SHEFFIELD - U.K.	100	48.0	15.0	20.0	24.0
TORINO - Italy	195	57.4	17.0	28.0	42.0
TOULOUSE - France	105	51.4	11	19	25

II. ADULTS, exposed to lead, living in inner urban area > 0.5 M

(code of survey 123,133,143,153,163)

zone	nb. of subjects	% of women	Percentile 50	90	98
BREMEN - Germany	36	52.8	11.5	16.8	18.0
GLASCOW - U.K.	196	50.0	17	30	40.1

* inner and outer anas

III. ADULTS, non exposed, living in outer urban area > 0.5 M

(code of survey 213)

zone	nb. of subjects	% of women	Percentile 50	90	98
AMSTERDAM - N.L.	52	100.0	8.0	12.0	14.0
" - N.L.	50	0.0	11.0	18.0	24.0
BERLIN - Germany	48	60.4	7.0	14.0	17.0
Outer BIRMINGHAM-Sut.Coldf	100	54.0	11.0	18.0	21.0
BREMEN - Germany	26	57.7	9.0	14.0	21.9
BRUXELLES - Belgium	119	40.3	16	25	34
DUBLIN - Ireland	51	51.0	14.0	19.9	23.0
DUISBURG - Germany	167	40.7	14.0	21.0	27.0
HAMBURG - "	54	46.3	12.0	20.9	34.8
HANNOVER - "	27	48.1	8.0	16.0	19.9
Outer LEEDS -Kingston-UK	101	55.4	13.0	20.9	24.0
Outer LIVERPOOL - U.K.	100	63.0	14.0	21.0	31.0
Outer LONDON - Kingston-UK	158	22.8	12.0	18.2	24.0
Outer LONDON-Waltham Forest	197	51.8	10.0	14.0	22.2
Outer MANCHESTER - U.K.	101	50.5	17.0	25.9	31.0
NURNBERG- Germany	29	27.6	9.0	14.0	21.9
Outer SHEFFIELD - U.K.	100	52.5	13.0	19.0	21.0

IV. ADULTS, exposed, living in outer urban area > 0.5 M.

(cod of survey 223,233, 243,253, 263)

zone	nb. of subjects	% of women	Percentile 50	90	98
BERLIN - Germany	45	42.2	10.0	17.0	31.8
" "	110	51.8	12.0	17.9	20.0
DUISBURG - "	62	45.2	13.0	19.9	24.0
" "	103	58.3	13.0	21.0	25.0
HILLINGDON - U.K. -M4	103	51.0	16.0	22.7	24.0
Lb BRENT North Circular Rd U.K.	192	49.9	11.0	17.0	22.2

V. ADULTS, non exposed, living in inner urban area < 0.5 M.

(code of survey 313)

zone	nb. of subjects	% of women	Percentile 50	90	98
ANVERS - Belgium	119	32.8	17	25	30
BOCHUM - Germany	34	50.0	12.0	19.7	33.8
CHARLEROI - Belgium	117	47.0	18	26	32
GAND - "	123	31.7	15	24	32
KIEL - Germany	89	40.4	11.0	16.0	18.0
LIEGE - Belgium	120	31.7	19	26	32
LUXEMBOURG - G.D.Luxembourg	111	46.8	between 12-14	between 18-20	between 22-24

VI. ADULTS, exposed, living in inner urban area < 0.5 M.

(code of survey 323,333, 343,353, 363)

zone	nb. of subjects	% of women	Percentile 50	90	98
BOCHUM - Germany	38	50.0	13.0	20.0	31.0
FRANKFURT a.M. - Germany	20	70.0	13.0	19.8	23.9
SAARBRUCKEN - Germany	56	57.1	13.5	19.9	26.9
TONGRES - Belgium	90	45.6	15	21	26
VERVIERS - "	121	43.0	24	39	59

VII. ADULTS, non exposed, living in outer urban area < 0.5 M.

(code of survey 413)

zone	nb. of subjects	% of women	Percentile 50	90	98
AHLEN - Germany	87	52.8	9.0	15.9	20.0
BOCHUM - "	165	46.7	13.0	19.0	23.0
NORDBADEN-KARLSRUHE-PFORZHEIM - Germany	22	36.4	9.5	17.0	21.0
STUTTGART - Germany	45	80.0	6.0	10.0	14.0

VIII. ADULTS, exposed, living in outer urban area < 0.5 M.

(code of survey 423,433, 443,453, 463)

zone	nb. of subjects	% of women	Percentile 50	90	98
AHLEN - Germany	29	58.6	8.0	12.0	17.9
AHLEN - "	33	48.5	7.0	13.8	21.0
Bassin industriel ANVERSOIS Belgium	120	36.7	17	26	32
BOCHUM - Germany	78	57.7	11.0	17.0	25.0
BOCHUM - "	34	52.9	12.0	19.8	27.9
Bassin Industriel LIEGEOIS Belgium	118	20.3	19	25	32
Paderno Dugnano - Italy	97	76.2	17.0	30.0	48.8
SASSUOLO - Italy	90	46.7	21.0	35.9	47.0
VENEZIA (Murano) - Italy	224	72.3	17.0	30.0	41.0
VENEZIA (") - "	124	79.0	16.0	25.0	33.0

IX. ADULTS, non exposed, living in rural area

(code of survey 513)

zone	nb. of subjects	% of women	Percentile 50	90	98
AHLEN - Germany	59	47.5	12.0	21.8	23.0
DULMEN - "	156	56.4	13.0	22.0	29.0
HUSUM - "	60	60.0	7.0	10.0	14.0
IDSTEIN - "	21	52.4	13.0	43.3	54.9
Sud NAMUR - Belgium	123	39.8	18	25	31
RUDESHEIM - Germany	25	48.0	15.0	20.0	26.0
SAARBRUCKEN - "	45	60.0	11.0	17.0	21.0

X. ADULTS, exposed, living in rural area

(cod of survey 523,533, 543,553, 563)

zone	nb. of subjects	% of women	Percentile 50	90	98
AHLEN - Germany	41	58.5	13.0	18.0	26.9
ASBACH/LIMBACH - Germany	201	52.2	11.0	22.0	41.0
DULMEN - Germany	106	56.6	13	21.9	29
DULMEN - "	24	45.8	14.0	16.9	19.0
GALWAY - Ireland	31	90.0	8.5	11.0	18.8
LIBRAMONT - Belgium	127	43.3	19	27	33

XI. CHILDREN, non exposed, living in inner urban area > 0.5 M.

(code of survey 111)

zone	nb. of subjects	% of women	Percentile 50	90	98
AMSTERDAM - Netherlands	52	54	14	22	24
BREMEN - Germany	56	51.8	10.0	13.9	16.0
NURNBERG - "	22	45.4	11.0	13.0	15.0
ROTTERDAM - Netherlands	100	51	16.0	25.0	33.0

XII. CHILDREN, exposed, living in inner urban area > 0.5 M.

(code of survey 121, 131, 141, 151, 161)

zone	nb. of subjects	% of women	Percentile 50	90	98
DEN HAAG - Netherlands	103	45.6	18.0	25.0	32.0
FRANKFURT a.M. - Germany	51	52.9	14.0	19.0	24.0
FRANKFURT a.M. - "	24	29.2	15.0	17.0	25.8
MUNCHEN - "	30	43.3	11.5	21.9	25.0
MUNCHEN - "	95	44.2	12.0	16.0	21.0
NURNBERG - "	30	40.0	11.0	13.0	15.0
Tower Hamlets - major road U.K.	182	42.9	18.0	24.0	29.0

XIII. CHILDREN, non exposed, living in outer urban area > 0.5 M.

(code of survey 211)

zone	nb. of subjects	% of women	Percentile 50	90	98
AMSTERDAM - Netherlands	58	54	11.0	16.0	21.0
BREMEN - Germany	41	56.1	9.0	11.9	16.0
DUISBURG - Germany	81	44.4	13.0	24.9	42.8
HANNOVER - "	50	44.0	9.0	12.0	14.0
NURNBERG - "	42	42.9	10.0	12.0	15.0

XIV. CHILDREN, exposed, living in outer urban area > 0.5 M.

(code of survey 221,231, 241,251, 261)

zone	nb. of subjects	% of women	Percentile 50	90	98
DUISBURG - Germany	31	51.6	9.0	20.7	28.9
DUISBURG - "	87	58.6	12.0	23.0	30.0
Lb GREENWICH - U.K.	400	52.0	13.0	20.0	27.0
HILLINGDON - M4 - U.K.	92	52.2	18.0	24.0	27.2
LEEDS (Thorpe) - U.K.	183	50.8	14.0	19.0	24.0
LEEDS (Tingley) - U.K.	277	51.1	10.0	14.0	19.0

XV. CHILDREN, non exposed, living in inner urban area < 0.5 M.

(code of survey 311)

zone	nb. of subjects	% of women	Percentile 50	90	98
BOCHUM - Germany	23	47.8	12.0	15.0	18.0
KIEL - "	37	54.1	10.0	13.0	16.0
LUXEMBOURG - G.D.Luxembourg	31	51.6	between 10-12	between 14-16	between 26-28

XVI. CHILDREN, exposed, living in inner urban area < 0.5 M.

(code of survey 321,331, 341,351, 361)

zone	nb. of subjects	% of women	Percentile 50	90	98
BOCHUM - Germany	25	56.0	10.0	18.0	20.0
CHESTER - U.K.	99	40.4	20.0	30.0	45.1
DARTFORD - U.K.	57	40.4	14.0	22.0	31.6
ELLESMERE PORT - U.K.	66	53.0	14.0	21.8	25.8
GRAVESHAM - U.K.	61	47.5	15.0	21.0	24.0
HAARLEM - Netherlands	50	66	16.0	21.0	26.0
LEEUWARDEN - Netherlands	53	52.8	12.0	17.0	18.0
SAARBRUCKEN - Germany	58	50.0	12.0	15.9	18.9
TILBURG - Netherlands	48	62.5	15.0	24.0	26.0

XVII. CHILDREN, non exposed, living in outer urban area < 0.5 M.

(code of survey 411)

zone	nb. of subjects	% of women	Percentile 50	90	98
AHLEN - Germany	31	45.2	7.0	10.0	15.9
BOCHUM - "	170	51.7	10.0	16.0	19.0
Group 4 - Denmark	20	55	8.5	10.0	11.0
Group 5 - "	14	14.3	6.1	10.0	11.0
STUTTGART - Germany	26	34.6	8.0	12.0	15.9

XVIII. CHILDREN, exposed, living in outer urban area < 0.5 M.

(code of survey 421,431, 441,451, 461)

zone	nb. of subjects	% of women	Percentile 50	90	98
AHLEN - Germany	27	66.7	7.0	12.0	17.0
BOCHUM - "	23	52.2	10.0	15.9	18.0
BOCHUM - "	78	43.6	10.5	17.0	22.9
Group 1 - Denmark	11	33.4	15.8	22.0	29.0
Group 2 - "	24	50	9.8	15.0	16.0
Group 3 - "	39	61.5	8.8	12.0	15.0
DUBLIN - Ireland	22	40.9	15.0	20.9	23.0
GOSSLAR - Germany	48	56.2	16.0	32.0	56.6
Market HARBOROUGH - U.K.	127	43.3	15.0	23.0	29.0
NEWPORT (Gwent) U.K.	170	41.4	16.0	22.0	24.6
SASSUOLO - Italy	108	46.3	17.0	23.0	28.0
VENEZIA (Murano) Italy	206	46.6	15.0	19.0	25.0
VENEZIA (") "	370	53.5	15.0	20.0	25.0
WIESBADEN - Germany	24	41.7	8.0	14.0	17.0

XIX. CHILDREN, non exposed, living in rural area

(code of survey 511)

zone	nb. of subjects	% of women	Percentile 50	90	98
DIESSEN/HILVARENBEEK- N.L.	51	45.1	12.0	16.0	20.0
DULMEN - Germany	188	54.8	14.0	20.0	25.0
HUSOM - "	40	35.0	6.0	9.0	12.0
IDSTEIN - "	25	56.0	15.0	22.0	37.0
RUDELSHEIM - "	25	48.0	13.0	18.0	20.0
SAARBRUCKEN - "	50	52.0	10.5	12.9	13.0

XX. CHILDREN, exposed, living in rural area

(code of surv y 521,531, 541,551, 561)

zone	nb. of subjects	% of women	Percentile 50	90	98
BAD HARZBURG - Germany	94	53.2	15.0	21.0	24.0
BEERSE - Belgium	158	48.7	14	19	28
BUDEL - Netherlands	50	50	11.0	15.0	19.0
DULMEN - Germany	81	49.4	14.0	21.0	31.0
ENGIS - Belgium	101	43.6	18	24	27
GALWAY - Ireland	86	53.5	10.0	13.0	18.0

XXI. CHILDREN, exposed, (address unknown)

(code of survey -31)

zone	nb. of subjects	% of women	Percentile 50	90	98
BEVERLEY - U.K.	134	48.5	15.0	21.0	23.3
CHESTER - "	80	50.6	19.0	30.0	44.0
ELLESMERE PORT - U.K.	33	39.4	13.0	19.4	22.7
GRAVESHAM - U.K.	184	49.5	19.0	27.0	32.3
Lb GREENWICH - U.K.	87	50.6	14.0	21.0	26.5
LEEDS (Thorpe) - U.K.	66	53.0	16.0	27.0	36.7
Market HARBOROUGH - U.K.	50	56.0	16.0	23.0	26.0
NEWPORT (Gwent) - U.K.	51	47.1	19.0	25.9	30.9

XXII. PREGNANT WOMEN, non exposed, living in inner urban area > 0.5 M.

(code of survey 112)

zone	nb. of subjects	% of women	Percentile 50	90	98
PARIS (Maternité) - France	27	100.0	14	19	20
TOULOUSE (Maternité)- "	76	100.0	6	13	27

XXIII. PREGNANT WOMEN, non exposed, living in inner urban area 0.5 M or in rural area

(code of survey 312,512)

zone	nb. of subjects	% of women	Percentile 50	90	98
LUXEMBOURG - G.D.Luxembourg	23	100.0	7	11	13

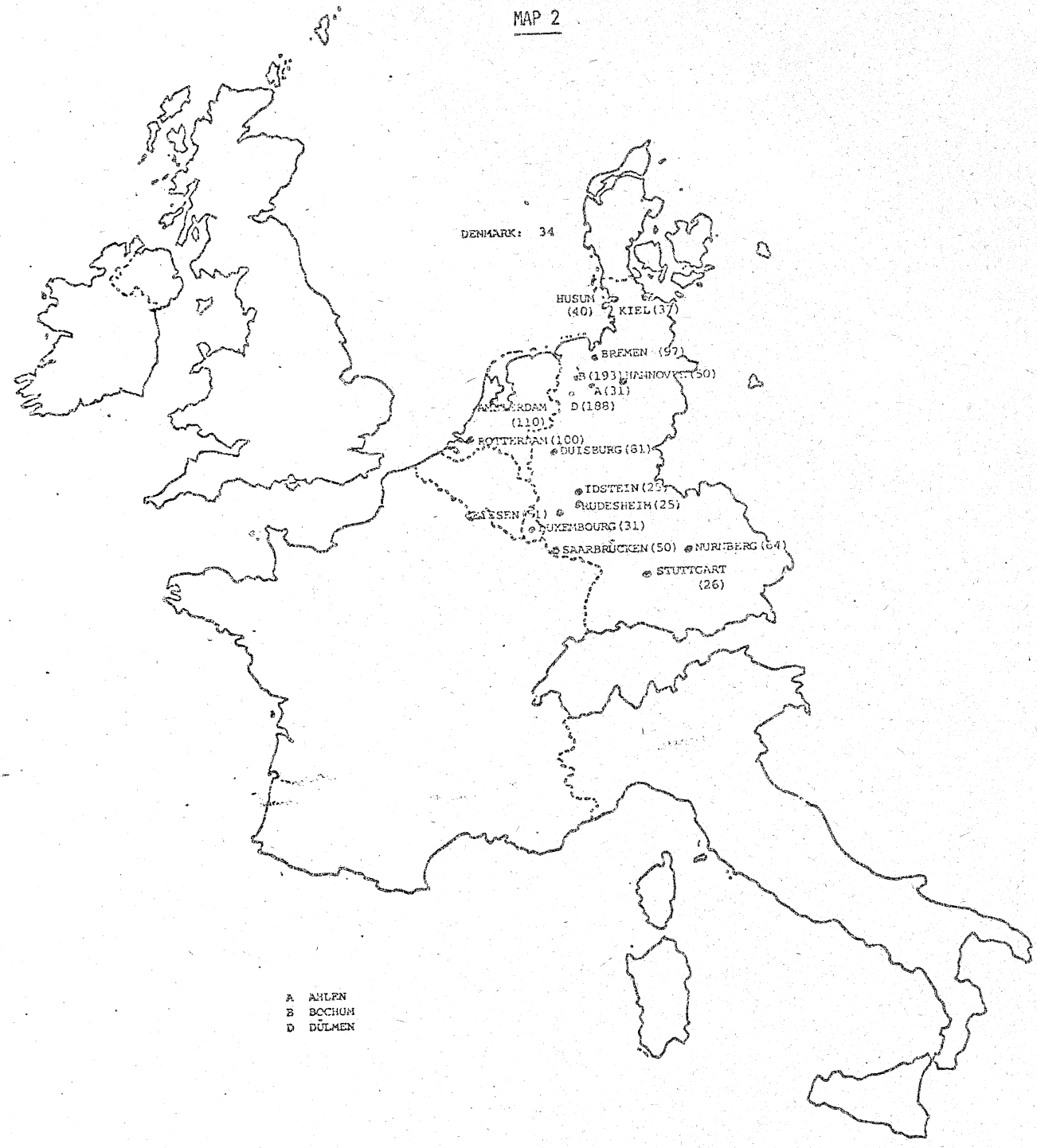
MAP 1

A GENT
B ANTWERPEN
C BRUXELLES
D CHARLEROI
E NAMUR
F LIEGE
L LUXEMBOURG

Adults non exposed to lead - localisation of zones

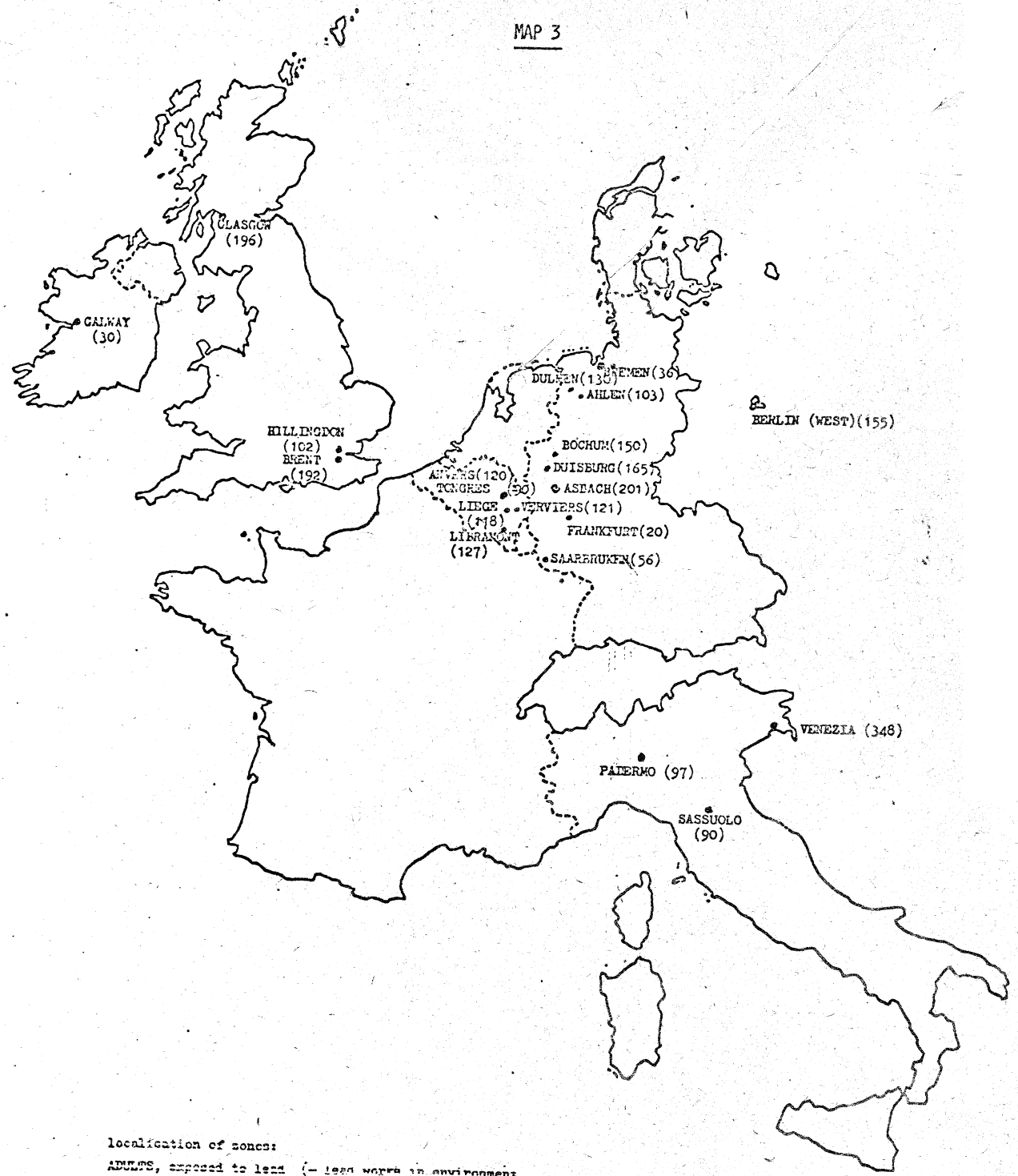
in brackets: number of subjects examined

MAP 2



Children non exposed to Lead

MAP 3

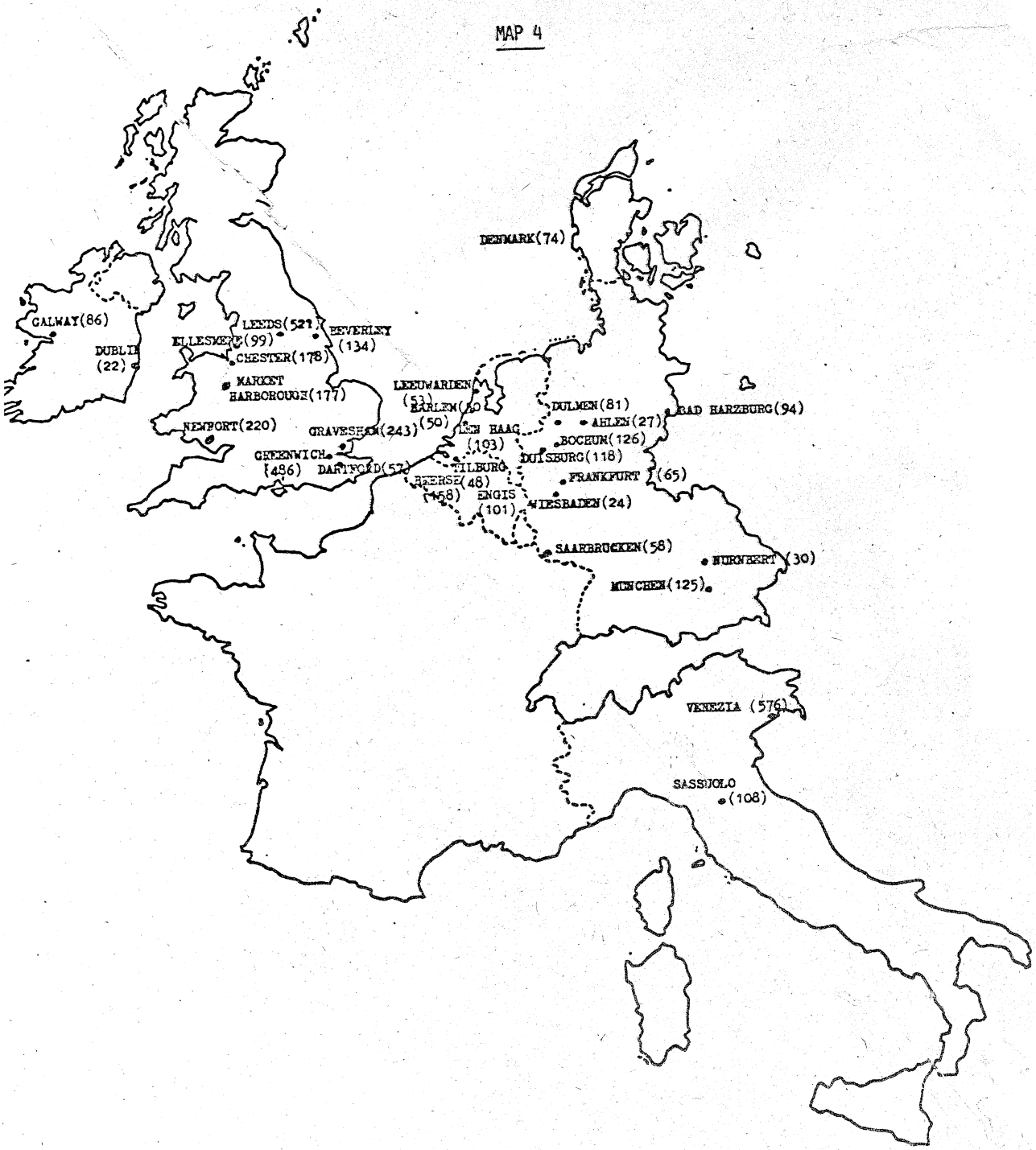


localication of zones:

ADULTS, exposed to lead (- lead works in environment
(- lead workers
(- lead pipes
(- busy roads
(- naturally high Pb level

in brackets: number of subjects examined

MAP 4



localisation of zones:

CHILDREN exposed to lead

in brackets: number of subjects examined