

# **COMMISSION OF THE EUROPEAN COMMUNITIES**

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## COMMUNICATION FROM THE COMMISSION TO THE COUNCIL

concerning the objective evaluation of the risks to human  
health from pollution by some persistent organo-chlorine  
compounds

## General

1. In the Programme of Action on the Environment\* (Part II, Title I, Chapter 1) organo-halogen compounds are considered as first category pollutants for priority investigation.

The Commission is required to submit to the Council the results of its work on the objective evaluation of the risks to human health and to the environment from pollution by the organo-halogen compounds.

This communication covers the various aspects outlined and contained in the above mentioned chapter of the Action Programme. It seeks to establish the consequences to public health of the use of these compounds and therefore does not deal with the consequences to the environment nor with the legislative procedures already taken or in the course of being considered by the Council of Ministers.

2. The Commission was asked to undertake as quickly as possible the following tasks:
  - compilation of as complete a bibliography as possible on the effects of the pollutants under consideration and a critical analysis of this information;
  - determination of criteria for certain pollutants;
  - standardization or harmonization of the measuring methods and instruments, so as to render the results of pollution measurements in the Community comparable.
3. After an initial evaluation of the problems involved it was decided to:
  - limit the studies to the most significant organo-chlorine compounds for which sufficient data is available
  - deal with ecological criteria separately,
  - study the other organo-halogen compounds as and when sufficient data becomes available.
4. To perform this work the Commission has:
  - held meetings of national experts,
  - made an overall survey of the available information for the period from 1968 to 1972 on the pollution levels of those persistent organo-halogenated compounds measured in:
    - various environmental media and in foodstuffs
    - in human fats and in maternal milk.

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\* O.J. C112 of 20.12.73

- performed a collaborative exercise in the determination of organochlorine residues in biological materials,
  - carried out a preparatory study for establishing criteria for humans for organochlorine compounds i.e. pesticides and their metabolites.
  - organized a European colloquium on the "Problems raised by the contamination of man and his environment by persistent pesticides and organo-halogenated compounds".
5. This communication is in the nature of an interim report which summarises the results of the tasks so far performed. A list of the reference documents that have been used for this communication is detailed in the annex.
6. This report contains the following main sections:
- I The content of organo-halogen compounds in water, air and foodstuffs and methods of analysis.
  - II Comparability of analysis methods.
  - III Pesticide residues in human tissues.
  - IV Criteria (Dose/Effect Relationships) for humans.
  - V Conclusions.
- I The content of organo-halogen compounds in water, air and foodstuffs and methods of analysis
1. The study entitled "The content of organo-halogen compounds detected between 1968 and 1972 in water, air and foodstuffs and the methods of analysis used in the nine Member States of the European Community", (1 of Annex) gave priority consideration to the following list of compounds:
- Diieldrine (HEOD)
  - DDT (pp'DDT + op'DDT) + DDD (pp'DDD or TDE) + DDE (pp'DDE)
  - Aldrine (HHDN)
  - Hexachlorobenzene (HCB)
  - Lindane (γBHC)
  - PCB
  - Heptachlor
  - Heptachlor epoxyde
  - BHC (α, β and δ)
2. Organo-chlorine pesticide residues are present in the air, water and soil of Europe, as well as in most of its foodstuffs of animal and vegetable origin.
3. Because of their persistent nature and application and the priority accorded to them in survey work, γBHC, DDT and its metabolite DDE, and diieldrin are the most frequently quoted organochlorine pesticides of those mentioned in this study.
4. It has been shown that the dust in the air in various places in Europe contains traces of the insecticides γBHC, diieldrin and DDT in amounts varying between 0.0001 and 0.001 μg/kg dust. Rain-water, like large rivers which are constantly discharging these residues into the sea, can contain levels which are a hundred times greater. Analyses of underground waters have produced in general negative results except when accidental pollution has taken place.

Because of the sea's dilution capacity and of its various tidal movements, measurement findings on concentration levels are often negative; nonetheless, the presence of these residues in high levels, varying from a few hundredths of a mg/kg to several mg/kg, found in salt-water fish is indicative of their presence in the sea.

There is insufficient data available concerning marine sediments, although data from Belgium showed residues of  $\gamma$ BHC, dieldrin, endosulfan, DDE and DDT present in North Sea sediments.

5. As large amounts of DDT, etc. accumulate inside fish which have lived in waters containing very small traces of persistent organochlorine pesticides, there is a need for carefully following the situation with regard to the concentration of these pollutants in the aquatic food chain.
6. In view of the different efficiencies of conventional methods for the removal of organochlorine traces from waters which are destined to be used for the production of drinking water, these waters should be protected against pollution by organochlorine compounds and adequately monitored.
7. DDT in particular, although not regularly used in fruit and vegetable growing, occurs in exceptionally high amounts in a small but consistent proportion of samples, indicating clearly the intermittent, and substantial presence of this pesticide in foodstuffs.

The treatment of fruit and vegetables by organochlorine pesticides, which is carried out in the world's fields and orchards, makes these foods potential vectors of these compounds. Despite the efforts of laboratories in various countries, the monitoring which is carried out is far too limited considering the volume of trade in these perishable foodstuffs, which come from many different places and which are part of our daily diet in Europe.

8. The levels reported in foods from the very restricted surveys cannot be considered representative of the overall situation particularly as local conditions are subject to change.

Nevertheless, they do show that the tolerances at present in force in the Member States are rarely exceeded.

9. The use of aldrin, dieldrin and heptachlor in the treatment of soils resulted in these pesticides, especially dieldrin, being found in root vegetables and potatoes and consequently in dairy produce and meat. The use of dieldrin was discontinued when residues were observed, but no exact determinations were made of the amounts present in fruit and vegetables.

10. Studies on poultry and eggs revealed that the feeding-stuffs used in poultry rearing were a major cause of their contamination.

Dairy products and meats are still a regular source of organochlorine pesticide residues in the diets of Europeans, and indicate partly the effects of contaminated animal feeding stuffs. As these feeding-stuffs are a source of organochlorine compounds, they should be subjected to adequate monitoring and when imported to strict entry conditions. The same applies to imported food directly consumed by humans, such as cocoa and imported cereals.

11. An inventory of the methods of analysis used for organochlorine residues in foodstuffs and environmental media showed that several techniques were in use as a result of numerous factors such as the availability of laboratory equipment and the orientation of individual laboratory research.

## II Comparability of analysis methods

1. The study entitled "A European Community study on the determination of organochlorine pesticide residues in fatty materials" (2 of Annex), took the following organo-chlorine compounds into account:  
Hexachlorobenzene (HCB)  
 $\alpha$ -,  $\beta$ - and  $\gamma$ -hexachlorocyclohexane (HCH)  
Dieldrin  
Heptachlorepoxyde (HEPO)  
p.p'-DDE  
TDE (= p.p'-DDD)  
o.p'-DDT  
p.p'-DDT  
(aldrin, heptachlor, chlordane and endrin were considered to be of no importance for the purpose of this study).
2. From a questionnaire on analytical methods it appeared that essentially five different methods were in use among the participating laboratories. There was no reason to suppose that one of those methods was superior to any of the others for the determination of the HCH-isomers, dieldrin, HEPO and the DDT-complex. For the determination of HCB, however, methods using liquid-liquid partitioning in the clean-up step could give rise to erroneous results.
3. The analytical methods for spiked samples showed fair to good reproducibility for  $\alpha$ -HCH,  $\beta$ -HCH, dieldrin, HEPO, p.p'DDE, o.p'DDT and p.p'DDT, but there was poor reproducibility for HCB.
4. The limits of detection reported by the different laboratories ranged from 0.005 ppm for HCB to 0.08 ppm for p.p'-DDT. Most laboratories reported 0.01 ppm as their limit of detection; higher detection limits were reported more specifically by laboratories involved in regulatory or monitoring programmes where quick screening of many samples on tolerance level was required rather than high sensitivity.

5. From the study on the market samples of rendered beef and pork fat it followed that on the low levels found relatively large variation coefficients occurred. This situation was to be regarded as normal for concentrations near the limit of detection.

### III Pesticide residues in human tissues

1. The study entitled "Pesticide residues in human fat and human milk in the nine Member States of the European Community (1969-1973)", (3 of Annex), give priority consideration to the following list of compounds:  
Dieldrin (HEOD)  
DDT (pp'DDT + op'DDT) + DDD (pp'DDD or TDE) + DDE (pp'DDE)  
Aldrin (HHDN)  
Hexachlorobenzene (HCB)  
Lindane ( $\gamma$ BHC)  
PCB  
Heptachlor  
Heptachlor epoxyde  
BHC ( $\alpha$ ,  $\beta$  and  $\delta$ )
2. The levels of DDT and metabolites, dieldrin, the isomers of BHC and heptachlorepoxyde, found in the fat of the population of the Member States did not differ greatly from the usual levels of populations outside the European Community.  
  
The level of DDT is invariably lower than the levels found in experiments conducted in volunteers which have been shown to be tolerable without causing any clinical symptoms and signs.
3. The data mentioned above justify the conclusion that there is no immediate risk to the inhabitants of Europe in the form of readily identifiable biological damage. However, a more detailed and elaborate survey in the years to come would be advisable to further evaluate the risk including the possible long term or delayed effects.
4. The evaluation of the effects of subtoxic doses requires more information, especially with regard to enzyme induction in human and animal tissues, as well as neurological and psychological effects. These effects should be studied for the organochlorine compounds separately and in combination.
5. Determining organochlorine pesticide residues in human fats would seem to be a valid method of depicting the exposure of a given population to organochlorine pesticides. As to the origin of these deposits it is generally accepted in the literature that organochlorine compounds found in human beings originated from food intake. However, a direct correlation between the residue levels in human fats and the exposure through food can not be drawn.

6. Due to the variety of techniques used to collect fat samples, to different methods of preparing samples, to difference in the social strata in which sampling was carried out and to differences in type of employment, health, sex and age, only tentative comparisons of the assembled data could be made.

An indication of the analytical problems is found in the results of the intercomparison programme run with some fat samples of food.

However these data do provide a starting point for an European survey based on standardized methods of sampling and sample preparation, of analytical methods and random selection of survey subjects. These data will permit a better assessment to be made and will show the trends in the levels of organochlorine compounds in human beings.

#### IV Criteria (Dose/Effect Relationships) for Humans

1. The definition of criteria establishing the relationship between a given exposure and an observable effect on human health is an important element in the objective evaluation of the undesirable effects or dangers inherent in any given nuisance.

Analysis of criteria permits in particular the identification of the levels of pollution or nuisance which have certain undesirable or harmful effects on man.

2. The study entitled "Preparatory Study for Establishing Criteria (Dose/Effect Relationships) for Humans on Organochlorine Compounds, i.e. Pesticides and their Metabolites" (4 of Annex) considered the following substances:

- DDT and its metabolites
- Aldrin, Dieldrin and Endrin
- Heptachlor and heptachlor epoxide
- Chlordane
- BHC and Lindane

3. Exposures much higher than occurs in the general population take place in those occupationally exposed. Ill effects have been observed in a number of individuals accidentally exposed to high dosage levels of certain of the above pesticides. Such effects have included neurological, dermatological, hematological and hepatic abnormalities but these effects described for compounds other than lindane need confirmation. Usually full recovery took place when the exposure ceased.
4. It is recognised that severe weight loss due to, for example, famine or ill health can increase blood levels of the above mentioned organochlorine pesticides in the European Community. Poisoning from such an occurrence is considered unlikely.

5. The results of chronic toxicity experiments in animals cannot always be extrapolated directly and have not yet been confirmed in man. However, animal experiments do confirm the acute effects.

When the above mentioned compounds are administered to various animal species the activity of hepatic microsomal metabolizing enzymes is increased. Such an effect has not been demonstrated in man at the levels of pesticides to which he is currently exposed.

High dosages have been shown to produce liver enlargement with histological changes in the hepatocytes in experimental animals.

Long-term feeding studies have shown that hepatic tumours are produced in mice by chlordane (recent review), DDT, aldrin, dieldrin, BHC and heptachlor; some of these tumours have shown malignant changes. There is a considerable controversy about the possible significance for man of the tumourogenic effect in mice of these compounds.

DDT and its metabolites have been shown to be mutagenic using certain test systems; other test systems have yielded negative results. Although these substances have been shown to increase perinatal mortality in experimental animals, no teratogenic effects have been observed.

## V Conclusions

1. Because of the difficulties of interpreting the data from experimental animals, and the lack of sufficient data on the long-term effects on man it is not possible at the present time to draw up criteria relating the levels to which man is exposed to possible effects.

To achieve this a considerable amount of research may be essential if man's exposure to these pesticides justifies it. Careful consideration should be given to such a requirement at the present time in view of decreasing usage. Such research should be directed towards those organochlorine compounds which are likely to be increasingly used in the future.

2. Apart from the presence of organochlorine pesticides in the fatty tissues of the body, no abnormalities have been demonstrated in the general population in the European Community which are directly attributable to the pesticides.
3. Present information from Member States indicates that because of controls, the usage of these persistent organochlorine pesticides and man's exposure to them is decreasing. Nevertheless, because of the difficulties and uncertainties mentioned above concerning toxicological evidence in relation to these products, it is considered that



- a decreased usage of any of these persistent organochlorine pesticides should be recommended within the European Community,
- the strict control of emissions of organochlorine compounds should take place,
- and the control of residues of organochlorine compounds in food and animal feeding stuffs should be reinforced.

4. To verify that usage and levels of exposure continue to decrease, it is considered that appropriate periodic monitoring should take place.
5. In the absence of criteria the attention of the Member States is drawn to the usefulness of the Estimate of the safe level of intake of these compounds (Acceptable Daily Intake or ADI) drawn up by the FAO/ WHO Working Party of Experts on Pesticide Residues in Food. The Commission has already taken these into account in preparing its Proposal for a Council Directive relating to the fixing of maximum levels for pesticides in and on fruit and vegetables.

Thought should be given in the future to the use of such ADI's and to the possibility of utilizing other concepts (for example, blood and other tissue levels) for expressing safe levels of exposure to such pesticides.

6. In considering on the one hand the requirements laid down in the Environmental Action Programme, and on the other hand the difficulties and uncertainties mentioned above, the Commission will continue to review and assess the information available with regard to the problems discussed in this interim report.

Annex

Reference Documents

1. The content of organohalogen compounds detected between 1968 and 1972 in water, air and foodstuffs and the methods of analysis used in the nine Member States of the European Community. (Rapporteur R. Mestres).
2. A European Community study on the determination of organochlorine pesticide residues in fatty materials. (Rapporteur P. A. Greve).
3. Pesticide residues in human fat and human milk in the nine Member States of the European Community (1969-1973). (Rapporteur G. L. Gatti).
4. Preparatory study for establishing criteria (Dose/ Effect relationships) for humans on organochlorine compounds i.e. pesticides and their metabolites. (Rapporteur M. Mercier).
5. European Colloquium entitled "Problems raised by the contamination of man and his environment by persistent pesticides and organohalogenated compounds", held on 14 - 16 May 1974. (EUR 5196).