# ESTABLISHMENT AND REVIEWS OF ORIGINAL KEPONE ACTION LEVELS

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## INTRODUCTION:

### 1. Evolution of the Problem and Brief Chronology of EPA Response

In mid-1975, the Atlanta Center for Disease Control, in conjunction with Virginia , discovered that several Life Science Products Company (LSPC) workers were seriously ill due to massive occupational exposure to Kepone. Kepone residues from .02 to 60 parts per million (ppm) were found in both blood and sebum samples from all 28 hospitalized LSPC workers, in addition to one worker's wife who had also been hospitalized.

Kepone levels of 0.1 to 4 parts per billion (ppb) were found in the James River. Kepone residues ranging between 0.1 and 20 ppm were found in fish and shellfish in the James River, some from samples as far as 40 miles away. Bottom sediments, soils, and sludge were also tested with positive results. Filters gathered between March of 1974, and April 1975, from the State air sampler station located approximately 200 yards from LSPC operation contained residues ranging from 0.2 to 50 micrograms per cubic meter of air. Tap water from the Hopewell water supply was also tested; fortunately, no detectable levels of Kepone were discovered there. As a result of the water media samplings, Governor Godwin of Virginia closed the James River to fishing the following day.

On August 20, EPA Region III issued an order to LSPC under the authority of the Federal Insecticide, Fungicide and Rodenticide Act, to stop the sale or use of Kepone, as well as its removal from the premises. On February 3, 1976, a similar order was issued to the Baltimore facility of Allied Chemical Corporation.

EPA's Environmental Research Laboratory in Gulf Breeze, Florida, (ERL/GB) has established the cleansing ability (depuration) of transplanted seed oysters. Data obtained from the State and corroborated by ERL/GB indicate the James River seed oysters depurate Kepone. The James River supplied 90 per cent of all the seed oysters in Virginia, of which 50 per cent of that amount is exported. Seed oysters are transplanted to various growing areas and reach marketable size in two to three years.

In February 1976, EPA recommended to the FDA "action levels" or allowable temporary levels of pesticide residues used as enforcement guides, of 0.3 parts per million (ppm) of Kepone in the edible portion of shellfish (oysters and clams) 0.1 ppm in finfish, and 0.4 ppm in crabs. EPA also recommended a 0.03 ppm action level in processed oyster stew. These recommendations were made using classical estimate procedures for threshold effects described in the next section of this paper. At that time, EPA committed itself to further consideration of this action level for possible revision if new data warranted it.

2. Considerations in Establishing Current Action Levels

There are at least three major considerations in adoption of action levels. First, toxicological, i.e., human safety, considerations are overriding. Second, there are analytical and residue chemistry considerations, which are necessary to establish or confirm analytical method(s) to enforce the action level. A third consideration is economic loss, i.e., what percentage of the fish and shellfish production will be rendered unfit by the action level.

A. Toxicological Considerations

The procedure used by the Toxicology Branch of EPA-OPP's Registration Division to develop recommended action levels for Kepone in finfish, shellfish and blue crabs was analogous to the procedure used for establishing the acceptability of pesticide tolerances. The following data were reviewed when the Kepone action levels were originally recommended and were rereviewed for this reassessment:

1. Acute Studies
   a. Oral $LD_{50}$ - Feb. 9, 1959
   b. Dermal $LD_{50}$ - Feb. 9, 1959
2. Subacute Studies
   a. 21-Day Oral - Rat - Feb. 9, 1959
   b. 90-Day Oral - Rat - Feb. 9, 1959
3. Chronic Studies
   a. 2-yr. Rat Feeding - July 1961
   b. 2-yr. Dog Feeding - Feb. 1962
   c. Mouse Reproduction - 1965
   d. NCI Verbal Oncogenic Report - Fall 1975

The initial correspondence in our files dates back to 1958 and some reports are undated. Therefore the dates given above are approximations in some cases.

In summary, the original review of the data indicated that:

1. Kepone is not acutely toxic and would be placed in toxicity Category II for labeling purposes. This category classification gives no indication of the subacute and chronic toxicity of the chemical.

2. There is evidence that Kepone is a cumulative toxin at relatively low levels (approx. 5 ppm in rats) and that within a three month period 5 ppm produced a 10 ppm fat residue and 80 ppm produced a 400 ppm fat residue.

3. Tremors, characteristic of chlorinated hydrocarbons, occurred at 25 ppm in chronic feeding study. Testicular atrophy and estrogenic effects were evident at this level in rats and mice resulting in sterility in both sexes. Females appear more susceptable to Kepone in all mammalian species tested. Ten ppm is hepatotoxic in females.

4. In a two-year rat study, 10 and 25 ppm may have produced hepatocarcinoma in both sexes. Preliminary information from NCI lends credence to this suspicion. Kepone produced a 24% incidence in female rats and approximately 80% in both sexes in mice at levels from 5 to 40 ppm. It appears that Kepone must be considered as a highly suspect carcinogen.

5. At 1 ppm in the rat a slight increase in proteinuria was noted and the severity increased with dose. Therefore the NEL of 1 ppm in rats reported by Allied Chem. is questionable.

6. Preliminary analysis of Kepone residues in shell fish and fin fish indicated levels near and above the questionable rat NEL.

The recommended Kepone action levels for fin fish, shell fish and crabs were developed in the following manner using a method analogous to tolerance acceptability calculations.

A. Determination of Maximum Permissible Intakes (MPI)

   1. Using the questionable 1 ppm "no effect level" from the two year rat feeding study and several safety factors (SF) a MPI was calculated for a 60 kg human. (1 ppm in rat diet = 0.050 mg/kg body weight/day)

| Safety Factor | SF Value (Rat) | MPI (Man, 60K) |
|---|---|---|
| | mg/kg bd. wt/day | mg/day |
| 100 | 0.0005 | 0.03 |
| 500 | 0.0001 | 0.006 |
| 1000 | 0.00005 | 0.003 |
| 2000 | 0.000025 | 0.0015 |

2. Sample calculations:

a. Determination of safety factor value

$$\frac{0.050}{1000} \text{ mg/kg/day} = 0.00005 \text{ mg/kg/day}$$

b. Determination of MPI

0.00005 mg/kg/day X 60 kg = 0.003 mg/day

B. Determination of Food Factors (FF) for each of the food items in the daily diet of man. (FF = % in daily diet)

1. Fin Fish (Fresh and Frozen, edible weight)

a. Per capita consumption 1973*
5.1 lbs/yr X453.6 gr = 2313 gr/yr

b. Per capita consumption/day
2313 ÷ 365 = 6.34 gr

c. % of 1500 gr total daily diet
6.34 ÷ 1500 = 0.42%

2. Shell Fish (Fresh and Frozen, edible weight)

a. Per capita consumption 1973*
2.1 lbs/yr X 453.6 gr = 952.6 gr

b. Per capita consumption/day
952.6 gr ÷ 365 = 2.61 gr

c. % of 1500 gr total daily diet
2.61 ÷ 1500 = 0.17%

3. Blue Crabs

   a. Per capita consumption 1969**
      0.213 lbs/yr X 453.6 gr = 96.6 gr/yr

   b. Per capita consumption/day
      96.6 ÷ 365 = 0.26 gr

   c. % of 1500 gr total daily diet
      0.26 ÷ 1500 = 0.02%

4. References


   * Food Consumption, Prices, Expenditures Supplement for 1973 to Agri. Eco. Report No. 138, USDA-Eco. Res. Ser. Table 9, p. 17, Dec. 1974.

   ** USDC Nat. Marine Fisheries Ser. Circular 361 (1969).


C. Determination of the Theoretical Maximal Residue Contribution (TMRC) of the recommended action levels to the daily diet, assuming that the maximum allowed residue will be present in the food when consumed.

   1. Fin Fish (action level 0.1 ppm= 0.0001 mg/kg of diet)
      0.0042 X 1500 gr X 0.0001 mg = 0.0006 mg

   2. Shell Fish (action level 0.3 ppm = 0.0003 mg/kg of diet)
      0.0017 X 1500 gr X 0.0003 mg = 0.0008 mg

   3. Blue Crabs (action level 0.4 ppm = 0.0004 mg/kg of diet)
      0.0002 X 1500 gr X0.0004 mg = 0.0001 mg

D. Comparison of TMRC with the MPI to determine acceptability of recommended action level (SF = 1000).

| Food Item | Action Level | TMRC | MPI |
|---|---|---|---|
| | ppm | mg/Total Diet | mg/day |
| Fin Fish | 0.1 | 0.0006 | 0.003 |
| Shell Fish | 0.3 | 0.0008 | 0.003 |
| Blue Crabs | 0.4 | 0.0001 | 0.003 |
| | | T=0.0015 | |

In each case the recommended action level produces a TMRC lower than the MPI derived with a 1000SF and leaves room for additional action levels for other food items if the necessity arises (total TMRC = 0.0015 mg/day vs 0.003 mg/day).

b. Analytical and Residue Chemistry Considerations

The only previous tolerance actions on Kepone were a temporary tolerance of 0.1 ppm on potatoes (expired) and a current tolerance of 0.01 ppm on bananas. The banana tolerance represents analytical sensitivity and was based on the Registration Division's Chemistry Branch's assurance to Toxicology Branch that there would be no real residues in edible parts.

(a) The Regulatory method for bananas (PP# 0E0919), was published in the Pesticide Analytical Manual (PAM) Vol II, and validated on banana peel and pulp. The method's estimated sensitivity is 0.005 ppm. The principle of this method involves isopropanol/benzene extraction, fuming sulfuric acid cleanup, base partitioning, and MC or EC gas liquid chromatography (GLC). The procedure is said to be applicable for certain other fruits, vegetables, milk with modifications for oily samples.

(b) HERL method(s): The HERL procedure is actually a system of alternative extraction, cleanup, determinative, and confirmatory procedures have been used in various combinations. For fish and shellfish, the basic procedure was: extraction of 10g sample with 25% toluene/Et acetate, cleanup by micro Florisil column or gel permeation, or base partitioning. Measurement is by GLC with any of 5 optional GC columns and any of 4 detectors. Some analyses have been confirmed by GC/Mass spectrometry with chemical ionization.

The sensitivity of the overall procedure appeared to be about 0.01 ppm in fish and shellfish, judging from the residue values reported. However, based on conversation with Dr. Moseman, Analytical Branch, HERL, this sensitivity may not always be attainable. Raw data (chromatogram) has been requested from HERL so that it will be possible to gauge the minimum response in relation to background. The alternative procedures were used to provide additional assurance through comparison of results. Reasonable agreement on replicate samples by the alternative procedures was obtained on most samples and there is no reason to question accuracy of results.

(c) FDA multiresidue methods: Kepone had not been sought in any FDA regulatory program, including the Total Diet Study. Its behavior has not been sufficiently studied in the PAM (FDA) multiresidue method for chlorinated hydrocarbons. Preliminary studies indicate that it is not detected by the method, either because it is not eluted from the Florisil column or does not have a favorable partitioning co-efficient in the acetonitrile/hexane partitioning step. FDA Headquarters was then devising a method to be used by the District Laboratories in the current Kepone situation. It seemed likely that they would go with some version of the current multiresidue method to minimize impact on their pesticide program.

(d) Other methods: There have been a few reports in the literature of other methods for Kepone but these appeared to be of limited interest. (Arant, F.S.J Econ. Ent. 60:925-7, 1967)

3. Residues in fish and shellfish in James River area (HERL data)

Fin fish examined were fresh water or anadromous species only. Kepone residues ranged from 0.01-0.2 ppm in bottom feeders and trace to 3 ppm in predator fish. These residue values apparently are based on the whole gutted fish. Any action level adopted would be on a similar basis because the FDA Manual describes the fish sample to be "headed, gutted, and scaled." Separate analyses were made by HERL on entrails and liver with correspondingly higher residue findings.

No data were presented on salt water food fishes (flounder, striped bass, blues, seatrout) which might be expected within the sampling area. This omission has some practical significance in regards to setting action levels. Consumer hazards arising from fresh water fish could be controlled (without action levels) by imposing fishing restrictions on local waters, the salt water acting as an effective barrier to migration from the quarantined area. The risks from consumption of the migratory salt water food fishes taken after residence in the James estuary would have to be controlled by an action level implemented in a national surveillance program since the fish might be taken elsewhere in Chesapeake Bay or long the East Coast. Levels found in clams and oysters were comparable and ranged from 0.2 to 0.8 ppm. No analyses of crabs were made.

The available data (total of about 26 samples) did not permit any statistical evaluation as to distribution of residue levels in fish or shellfish populations within the contaminated area during the period of sampling. Neither was the sampling adequate to indicate residue decline rate. Both factors are important considerations in selecting an action level because they determine the extent of economic loss, i.e., a given action level renders x% of the fish population violative at a given time.

We had little or no information on any alterations Kepone may undergo in water or marine organisms. A rat metabolism study indicates it is fairly stable in mammals. The related compound Mirex is known to degrade under sunlight or UV light to Kepone and further Cl 9 and Cl 10 degradation products of Kepone.* On the basis of present information, Kepone per se must be considered the residue of concern in fish and the action level should reflect this.

*G.W. Ivie, H.W. Dorough, E.C. Alley, J. Ag Food Chem 22 no. 6, 1974

4. New Considerations for Revising or Continuing Action Levels
Current Action Levels

Subsequent to the above review the Toxicology Branch received the NCI Carcinogenesis Bioassay Report on Technical Grade Chlordecone (Kepone). A summary of the results, provided by NCI, confirming the suspicion raised by the two year rat study follows:

"A carcinogenesis bioassay of technical grade chlordecone (Kepone) was conducted using Osborne-Mendel rats and B6C3F1 mice. Chlordecone was administered in the diet for 80 weeks at two dose levels, with the rats sacrificed at 112 weeks and the mice at 90 weeks. The starting dose levels were 15 and 30 ppm for male rats, 30 and 60 ppm for female rats, 40 ppm for male mice and 40 and 80 ppm for female mice. As these dose levels were not well tolerated, the dose levels were reduced during the course of the experiment such that the average dose levels were as follows: 8 and 24 ppm for male rats, 18 and 26 ppm for female rats, 20 and 23 ppm for male mice and 20 and 40 ppm for female mice. Clinical signs of toxicity were observed in both species, including generalized tremors and dermatologic changes. A significant increase (P .05) was found in the incidence of hepatocellular carcinomas of high dose level rats and of mice at both dose levels of chlordecone. The incidences in the high dose groups were 7% and 22% for male and female rats (compared with 0 in controls for both sexes) and 88% and 47% for male and female mice (compared with 16% for male controls and 0 in females); for the low dose groups of mice the incidences were 81% for males and 52% for females. In addition, the time to detection of the first hepatocellular carcinoma observed at death was shorter for treated than control mice and, in both sexes and both species, it appeared inversely related to the dose. In chlordecone-treated mice and rats extensive hyperplasia of the liver was also found. The incidence of tumors other than in the liver for chlordecone-treated groups did not appear significantly different from that in controls."

More recent food consumption values were used for finfish and shellfish than in the first recommendation; therefore, the figures presented than differ slightly from previous derived quantities. The differences do not change the recommended action levels for each food item previously developed. With the exception of the NCI carcinogenesis Bioassay Report, summarized below, no new toxicological data has been received by the Toxicology Branch since the original recommendation.

In the previous evaluation it was concluded that an action level of 0.02 ppm for fish, clams and oysters could be supported with available analytical methods. This represented a bottom line figure subject to increase by toxicology and economic impact considerations. The figures which subsequently issued were 0.4, 0.3, 0.1 ppm on crabs, oysters and fin fish, respectively.

Given the present state of the methodology for Kepone, a 0.02 ppm action level could still be supported if new toxicology information requires such a reduction from present action levels. That is, residues on the order of 0.02 ppm can be measured when analytical procedures are carefully controlled. However, experience gained with the methods during the intensive 1976 sampling program, including an interlaboratory quality assurance (check sample) study, suggests that a level of 0.05 ppm should be the lowest level at which any regulatory action should be taken.

Detailed Considerations

1. Commodity definition

It is important that action levels clearly specific the sample portion to which it applies. The following corresponds to those used for tolerances and are found in FDA PAM Vol. I, Sec. 141.12.

(a) fin fish and eel discard head, tail, fins, scales, inedible bones and entrails, analyze with skin (except fish with inedible skin)

(b) oysters, clams: examine homogeneous mixture of meats and liquor. (exclude shell liquor.)

(c) crabs: Discard shell and viscera, examine edible portion including fatty deposits in wing tips. (for soft crabs use whole crab)

2. Chemical entity measured

Although certain rearrangements of Kepone-Mirex have been reported, there is still no information on significant metabolites occurring in marine organisms and the residue of concern is Kepone per se. It is measured against reference standard (EPA # 7) in tetrahydrate form (corrected to anhydrous Kepone.)

3. Improvements in methodology

Significant advancements have been made in Kepone methodology in 1976. The advancements, however, may be characterized as refinements and validation of available methods rather than any breakthroughs. Several analytical workshops between EPA (RTP, Gulfbreeze, and RD), FDA, Virginia State laboratories, and Maryland were instrumental in eliminating numerous and troublesome optional extraction, cleanup, and determinative steps employed in the various labs in early 1976. From these meetings there emerged a more or less standardized analytical method and useful agreement on sample preparation and use of reference standards.

The method of choice for fish, shellfish, and crabs is based on the Allied Chemical Co. method as described in PAM Vol. II for bananas. A modification of this method was devised by Chemistry Branch, RD, and used in the analyses of 60 fish samples for the State of Va. A paper on this method was presented by Mr. Watts, CHM at a symposium in Williamsburg VA. in May.

FDA was not successful in incorporating Kepone into their multiresidue schemes. They have devised for their regulatory program a modification of the same method (PAM II), described above (see program circular 7320.79A, attach. C). It is this method which will be used to enforce Kepone action levels and it would be adequate to enforce an action level of 0.05 ppm. Principle: isopropanol/benzene extraction, fuming sulfuric acid cleanup, base partitioning, and GC/EC detection.

Analysis of 1976 residue data on fish, shellfish, and crabs

Through the spring, summer, and fall of 1976 several major sampling programs were carried out. The first of these was coordinated by the Virginia Division of Consolidated Laboratory Services. The cooperating laboratories were RTP-EPA; Gulfbreeze-EPA, Registration Divison (CHM)-EPA, Annapolis-EPA, FDA Baltimore District and Virginia Institute of Marine Sciences (VIMS). Sampling in this program was mainly in the lower bay and tributaries. The State of Maryland established a Kepone Task Force and conducted sampling, mostly in the upper bay.

The FDA initiated a program calling for analyses of 304 samples of Kepone (and Mirex) through October 29, 1976. These samples were to be collected from commercial markets, with primary emphasis on Bay fish, but also some sampling of migrant bluefish along the east coast and some in the fire ant areas (Gulf Coast) to investigate possible Kepone residues from Mirex usage.

Much of the data from these programs seems to have been freely interchanged, but we are not aware of any comprehensive summary of the 1976 sampling program. Such a summary could provide a base for predicting the level of residues likely to occur in Bay fish populations in 1977, and most importantly, what percentage of the catch would fall within action levels.

Certain statements in the files indicate that such statistical analyses may have already been made. Example: Gov. Godwin "among all species of finfish tested.... samples above action level ranged from 7 to 16 ," (Richmond News Leader 10/13/76). Also, the National Fisheries Institute and Virginia Seafood Council (letter of 10/14/76, L.J. Weddig, Exec., Dir. in letter to J. Blanchard) says 14.2 of all species were above action level.

Attachment A is a statistical evaluation of the distribution of residues in fish, shellfish, and crabs. The evaluation is based on all the data available to us as of 12/23/76. It includes all of the residue data generated in the 1976 FDA regulatory program, data from the Maryland Kepone Task Force, and data from the program

coordinated by the Virginia Division of Consolidated Laboratory Services, including 60 analyses made by our CHM laboratory, RTP, and Gulfbreeze. The Virginia data may be incomplete.

The data base includes a total of about 470 analyses of various portions of 25 species taken from various locations.

4. Results of Reassessment and Recommendations

The Toxicology and Chemistry Branches have rereviewed all data on which the original action level recommendations were made and have also taken into consideration data received since those recommendations were forwarded. The latter include additional residue data and an NCI Chlordecone Carcinogenesis Bioassay report. The review confirms the original action level recommendations, 0.1 ppm finfish, 0.3 ppm shellfish, 0.4 ppm crab.

The toxicological review was calculated on the original basis of a 1000-fold safety factor applied to the rat chronic feeding study data. Some minor variations from the original were seen in the Toxicology Branch calculations due to the use of more recently developed dietary intake figures in the calculations. Because of the demonstrated carcinogenic potential of Kepone in two species of test animals, the lack of a clear cut "no-effect level" in the two year rat feeding study, and the evidence that Kepone is a cumulative toxin, no recommendation is made to revise the established Kepone action levels at the present time.

The major recommendation change from the Chemistry Branch Review, in light of additional experience with the analytical method, is to adopt 0.05 ppm (as opposed to 0.02 ppm) as the baseline enforcement action level subject to modification by toxicological or benefit/risk parameters. Acceptance of 0.02 ppm would require extremely careful control on the analytical method.

As part of the evaluation of current action levels, an independent study of risks and benefits was performed by scientists in the Office of Special Pesticide Reviews (attached). Emphasis was placed on the identification, articulation and measurement of variables, either health or economic related, which are affected by alternative regulatory options. Specifically, the paper presents an analysis of the human health impacts which might be associated with maximum Kepone exposure (residues equaling the current action levels) from Chesapeake Bay finfish, shellfish and blue crabs. Health impacts were evaluated using two currently accepted models for cancer assessment — the "one-hit model" and the "log-probit model" — under several alternative patterns of human seafood consumption. In an attempt to tie a measure of benefit to the seafood sector affected by Kepone action levels, the study also examined the total protein production for human consumption arising from Chesapeake Bay fisheries as well as other economic characteristics. The information contained in the Office of Special Pesticide Review's study will be used as input into the decision process regarding recommendations for Kepone action levels.

# Summary And Analysis Of The Currently Available Kepone Residue Data

## Introduction

Samples of Fin Fish and Shell Fish from the Virginia and Maryland Waters of the Chesapeake Bay and its Tributary Rivers have been collected in several major sampling programs conducted by the States Maryland and Virginia and the Food and Drug Administration and the Environmental Protection Agency. To our knowledge no complete summary of all the Kepone Residue analysis from these programs is available yet. However, the analytical results from over 600 samples collected in these programs were provided to us by Dr. Paul Corneliussen of FDA and Dr. Jack Blanchard of EPA. Of these samples adequate information concerning species, collection point and how the sample was prepared for analysis was available for 470 of these samples. These 470 samples represented about 25 different species of marine life. A discussion of these residue data are presented here.

Samples collected from the James River (up-stream from the James River Bridge) were considered separately from the Chesapeake Bay (including the Hampton Roads area). This was done because of the high levels found in the James River samples and because the State of Virginia has banned fishing in the James River. Consideration of data was further divided into fin fish; clams, oysters conch and muscles; and crabs, because it is on these commodities that the current action levels have been established.

In general the data for these samples showed markedly non-normal distribution such that approximately 70% of the reported values are below their respective arithmetic means. The third moments about the mean (a measure of skewness: it equals 0 for a normal curve and less than 0.5 for approximately random distributions) ranged from 4 to 5 for most of the distributions. Because of the non-normal distribution of these data the statical inferences that can be drawn are limited. However, the conclusions that can be drawn are discussed below.

## Fin Fish

Chesapeake Bay: Residue data and adequate background information for 193 samples representing 16 species of fin fish taken from the Chesapeake and its tributary rivers (except the James) were available. With the possible exception of shad no significant difference between species was detected.

Excluding the shad, the residue levels reported ranged from 0 to 0.86 ppm and averaged 0.056 ppm with a standard deviation of 0.114 ppm. The shad averaged 0.117 ppm with a standard deviation of 0.223 ppm. However, because of the non-normal distribution of the data no definitive conclusion can be reached as to whether this difference is significant. (See Conclusion below). 156 or 80% of the reported values were below the mean. Only 8% of the samples collected exceeded the current 0.1 ppm action level. Approximately 5% exceeded the 0.2 ppm level. No definitive conclusion as to what percentage of fish caught in the Bay would be expected to exceed the 0.1 ppm level can be made. However, these data appear to indicate that about 8-10% of the fish caught may be over the current action level.

James River: Residue data and adequate background information for 51 samples representing 10 species of Fin Fish taken from the James River were available. Residue levels reported ranged from 0 to 8.1 ppm. The average value for all James River Fin Fish was .931 ppm with a standard deviation of 1.85 ppm. Again almost 70% of the reported values were below the mean. 55% of all sample exceeded the current 0.1 ppm action level, and approximately 1/3 of the samples exceeded the 1 ppm level. The residue levels reported for the 25 shad samples taken from the James River were no higher than other species, in fact their average residue level was only 0.503 ppm. The data tend to indicate that the average residue level in Fin Fish taken from the James River would approach 1.0 ppm.

Clams, Oysters, Conch, and Mussels

Chesapeake Bay: Residue data for 110 samples of these shell fish taken from the bay were considered. Residue levels reported ranged from 0 to 0.76 ppm. The average value was 0.046 ppm with a standard deviation of 0.111 ppm. Again the distribution of residue values was badly skewed with 74% of all reported values below the mean. Only 2 samples or about 2% bore residues above the current 0.3 ppm action level. The data appear to indicate that residue levels in these shell fish taken from the Bay are comparable to the levels in Fin Fish.

James River: Residue data for 55 samples of these shell fish taken from the James River are available. The reported residue levels ranged from 0 to 0.51 ppm. The average residue level was 0.209 ppm with a standard deviation of 0.128 ppm. 22% of these samples exceeded the current 0.3 ppm action level. The data tend to indicate that the levels in this class of shell fish taken from the James River will be less than the corresponding levels in Fin Fish.

Crabs

Chesapeake Bay: Residue data and adequate background information are available for 48 samples of crabs. The edible portions of both hard and soft crabs were included. The soft crab data was included in these data because of the limited number of samples available. The reported reside values ranged from 0 to 3.44 ppm. The residues averaged .261 ppm with a standard deviation of 0.551 ppm. Again almost 70% of the reported values were below the mean. However, 19% of samples were above the current 0.4 ppm action level and 13% were above the 0.5 ppm level. These data tend to indicate that average residue levels in crab meat from crabs taken from the bay will approach 0.3 ppm and that about 20% of the crabs may exceed the current action level.

James River: Only five samples of crabs taken from the James River are available. Residue values ranged from 2.04 to 3.10 ppm and averaged 2.69 ppm.

In conclusion the data demonstrate a markedly non-normal distribution: thus, indicating that there were additional parameters effecting the Kepone residue levels in fish than were included in our analysis. The first parameter considered was geographical location, but further dividing of the data into smaller areas for consideration provided little improvement in the distribution of residues. Because Kepone is a persistent compound the length of time a specimen is exposed (generally its age) would be expected to be an important factor. However, information as to age or even weight of samples was only available for a portion of the data, and thus could not be included in our considerations. Also the season of the year a sample was taken in some species could significantly effect the resulting residue levels.

Thus, the data indicate that the inferences that can be drawn from these data are very limited because it can not be demonstrated that the undefined parameters effecting the distribution of residues will be consant for any subsequent samplings. Perhaps, when a complete summary of all the samples collected in the various state and federal sampling programs is available a better delineation of parameters effecting residue levels will be possible, and more definitive predictions regarding residue levels can be drawn.

Additional Kepone residue samples were collected by the Food and Drug Administration from the waters of the Atlantic Ocean and the Gulf of Mexico. The residue data from the analyses of these samples are also available. However these data were not included in this evaluation, because of the much lower exposure of these samples to Kepone residues.

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