# USING PESTICIDE DATA FOR EXPOSURE ASSESSMENT: FDA PESTICIDE RESIDUE MONITORING PROGRAM

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**Abstract**

The Food and Drug Administration (FDA) is responsible for enforcing tolerances established by the Environmental Protection Agency (EPA) for pesticide residues in foods shipped in interstate commerce. FDA also determines dietary intakes of pesticide residues in food through its Total Diet Study, in which foods are collected at retail nationwide, prepared for consumption, and analyzed for residues. These different but complementary approaches have provided information over the years that demonstrates the safety of the food supply with regard to pesticide residues. Findings from the Total Diet Study show relatively low dietary intakes of pesticide residues in foods as consumed when compared with estimated safe intake levels established by governmental and international organizations. No detectable residues were found in about two-thirds of the nearly 19,000 samples analyzed as part of FDA's enforcement monitoring in 1989.

**Regulatory Responsibilities for Pesticides**

Several federal agencies and their state counterparts share responsibilities for regulating pesticides. The Environmental Protection Agency (EPA) registers and approves pesticide uses and, if use of a pesticide may result in residues in foods, establishes tolerances. (A tolerance is the maximum amount of a residue expected in a food when a pesticide is used according to label directions, provided that the level does not present an unacceptable health risk.) The Food and Drug Administration (FDA) is responsible for enforcing these tolerances, which cover pesticide residues remaining in or on domestic or imported foods shipped in interstate commerce, except for meat and poultry, for which the U.S. Department of Agriculture (USDA) is responsible. States are responsible for similar regulation of foods shipped in intrastate commerce.

FDA has conducted a large-scale monitoring program for pesticide residues in foods since the early 1960s (Duggan, 1968). Currently, the program has two principal elements: (1) enforcement (commodity) monitoring, to measure residue levels in domestic and imported foods to enforce tolerances or other legal limits; and (2) the Total Diet Study, to determine dietary intakes of pesticides and other selected chemicals.

**Enforcement Monitoring**

Although the data are not generally appropriate for use in assessing actual exposure to pesticide residues in the diet because of the regulatory nature of the sampling and analyses, FDA's enforcement monitoring efforts and findings deserve mention here, since these data may be employed by EPA and others in assessing potential dietary risk resulting from pesticide residues in foods. The primary objective of this monitoring element is to enforce tolerances established by EPA. A very important ancillary benefit is that important information is developed on the incidence and levels of pesticide residues in the U.S. food supply. This information provides FDA with an overview of pesticide residues in foods and is a measure of the effectiveness of the U.S. regulatory system. The monitoring results are summarized and made available to EPA, other government and international agencies, and the general public through the scientific literature or other means.

Monitoring data represent characteristic pesticide residue levels in raw agricultural commodities generally sampled at the "farm gate", and thus are not representative of typical consumers' actual dietary exposure through ready-to-eat foods. Residue levels found are commonly much higher than would be encountered by consumers, since the whole (including inedible portions), raw, unwashed commodity is generally analyzed (pursuant to law) at times nearer to harvest than when it would be offered at retail points of sale. The information generated from this segment of the program is of greatest value in assessing maximum potential dietary exposure to pesticides in contrast with the "real-world" exposure depicted by FDA's Total Diet Study.

Domestic samples are collected as close as possible to the point of production in the food distribution chain, since the emphasis is on enforcement of tolerances established by EPA. Sampling at an early stage of distribution provides the best opportunity to effect timely regulatory follow-up, if such is indicated. Import samples are collected at the point of entry into the U.S. Special emphasis is given foods imported from Mexico, since large quantities of fresh and processed foods are involved, especially during the winter months.

FDA's 1989 enforcement monitoring involved collection and analyses of samples representing nearly 19,000 shipments of food (FDA, 1990). Imported foods comprised nearly 60% of the total, reflecting FDA's increased emphasis on imports. A decade ago, the reverse was true; about 60% of the monitoring was devoted to domestic sampling and analyses (FDA, unpublished data). Shipments from about 80-90 different countries are sampled each year. The foods are analyzed for a wide variety of possible pesticide residues. Of the approximately 250 pesticides (270 in 1989) that would be measured if their residues were present, about 110 have been found in recent (108 in 1989) years (FDA, 1988; 1989). There are currently about 300 pesticides with U.S. tolerances on foods, as well as a number of other pesticides and related chemicals that may be present as residues. Because of the great number of possible pesticide-commodity combinations, selective monitoring of foods of dietary importance is carried out to achieve the most effective consumer protection.

Over the past several years, no residues have been found in nearly 60% of the food samples examined; about 1% of all samples contained residues that exceeded established tolerances. An additional 1% of domestic and 3-5% of imported food samples had pesticide residues for which no tolerance had been established for the particular pesticide/commodity combination. Although residues in this category are considered illegal or violative because no tolerances were established for those specific pesticide/commodity combinations, often tolerances exist for similar, but not identical commodities. These related tolerance levels are often significantly higher than those found in any given violative sample in the "no tolerance" category. These data indicate that pesticides are not often used in a manner that results in excessive residues. It must also be emphasized that above-tolerance residues, while illegal, do not generally pose a risk to the consumer, since large safety factors are inherent in EPA's tolerance-setting procedures.

**Total Diet Study**

The second major component of FDA's pesticide monitoring program is the Total Diet Study, which was initiated in 1961 (Pennington and Gunderson, 1987). This approach, in contrast to the enforcement monitoring described above, provides the means to directly estimate dietary intakes of pesticide residues (intakes of industrial chemicals, heavy metals, essential minerals, and radionuclides are also determined). The intakes so determined are invaluable in assessing dietary exposure.

The primary purposes of this study are to determine the dietary intakes of the constituents cited above, compare them with established standards (see discussion below), and identify trends. The Total Diet Study also serves as a final check of the effectiveness of the U.S. regulatory system for pesticides (Gunderson, 1988).

Foods are purchased by FDA personnel in supermarkets or grocery stores in 3 cities in each of 4 geographic regions of the U.S. 4 times annually, yielding a total of 4 "market baskets" per year. The 3 like foods collected in each of the 3 cities are combined and prepared for consumption to produce 234 table-ready food items, which are then analyzed for residues of over 100 pesticides, as well as the other chemical types listed above. The details relating to the construction of the diets and the food lists have been described (Pennington, 1983). Because foods purchased at retail and prepared ready-to-eat generally are expected to contain very low levels of pesticide residues, the analytical methods used to analyze Total Diet Study foods are modified to permit quantitation at levels 5 to 10 times lower than those commonly used in FDA enforcement monitoring. The identities of the pesticides found are also confirmed by an alternative analytical method. The residue concentrations determined by these procedures are used to calculate the dietary intakes of the various analytes by 8 population groups; the intakes are then compared with established standards.

For pesticide residues, one set of standards with which comparisons are often made is the acceptable daily intakes (ADIs) of the United Nations' Food and Agriculture Organization (FAO) and the World Health Organization (WHO). An ADI is the daily dietary intake of a chemical which, if ingested over a lifetime, appears to be without appreciable risk (Food and Agriculture Organization of the United Nations, 1976). EPA also sets standards, termed reference doses (RfDs), which are estimates of total pesticide exposure to the human population (including sensitive subgroups) that are likely to be without appreciable risk of deleterious effects during a lifetime. The assumptions made by EPA in setting RfDs are somewhat different from those used by FAO/WHO in establishing ADIs; thus the EPA RfDs can be either higher or lower than ADIs. Both ADIs and RfDs are revised as new scientific information becomes available.

The dietary intakes for the pesticides found in the 1989 study are given in Table 1 for the infant, teen-age male, and older female. As can be readily observed, the intakes are generally manyfold lower than the FAO/WHO ADIs or the EPA RfDs; these findings corroborate those of earlier years. Current ADIs (Vettorazzi, 1985; Food and Agriculture Organization of the United Nations, 1986-1989) and RfDs (EPA, 1990) are listed for reference. ADIs and RfDs have not been established for all pesticides, and some include several chemicals which may be related because of their formation during manufacture or as a result of environmental degradation. The DDT group is a good example of the latter; this group includes the various isomers of DDT and its degradation products.

Of the more than 200 chemicals that can be determined by the procedures used, about 50 are typically found each year. Table 2 lists the 29 most frequently found pesticides in 1989 and their frequency of occurrence. Over the past 10 years, malathion and DDE have been the most frequently occurring pesticide residues. Malathion is widely used on many grains, fruits, and vegetables and has historically been found in one-fourth or one-fifth of the 234 Total Diet foods. While DDT is no longer permitted for use on foods in the U.S., its residues (primarily DDE) continue to be found at very low levels in many foods, primarily those of animal origin. As can be seen, none of the daily intakes approached established ADIs or RfDs.

Intakes of persistent chlorinated pesticides have declined steadily since cessation of their agricultural uses in the U.S. over a decade ago; however, residues of these pesticides continue to occur at low levels, particularly in foods of animal origin. Although not pervasive, low-level residues of some of the more recently developed pesticides are now appearing. Because these pesticides are generally not as stable as the older chlorinated pesticides, their residue levels in ready-to-eat foods are low, as are their dietary intakes.

For a number of analytes, the bulk of the intake is derived from a relatively small number of foods. For example, about 80% of the malathion intake typically stems from grain-based products, and nearly 100% of the vinclozolin intake is from residues on strawberries.

Assessment of dietary exposure resulting from pesticide residues in table-ready foods is complicated by several factors that do not generally affect dietary intake evaluations of most toxic elements and minerals determined in the Total Diet Study. These factors include the generally low (especially when compared to EPA tolerances) concentrations found (often near limits of quantitation), the highly variable levels, and the infrequent residue occurrences for many compounds. For these reasons, spurious findings can greatly influence the computation of intakes. Whether the total dietary intake of a pesticide results from few findings in few foods, or many findings in multiple foods, it is markedly affected by even a single finding at the EPA tolerance level, or even a fraction of it. For this reason, long-term (a several-year period) assessment of dietary exposure is preferable.

These influences are not as prevalent in evaluation of dietary intakes of toxic elements and minerals, which often are found in a wider variety of foods and at fairly constant levels in individual foods. These factors have a "leveling effect" on intakes; these analytes are not as significantly affected by variations in concentrations as are typical pesticide residues.

The effect of rare (but legitimate) pesticide findings on dietary intake can be shown. The 1989 data reflecting 4 market baskets show a malathion intake of 5.5 µg/day for the 14- to 16-year old male. If we consider a single additional residue finding on raw tomatoes at 8 ppm (the EPA tolerance level), the intake becomes 25.1 µg/day. Similarly, 2 findings on tomatoes at 8 ppm would raise the calculated intake to 44.7 µg/day for this population group. In the highly unlikely event of such occurrence, the daily intake would still be less than 4% of the ADI or RfD.

This effect is more pronounced in cases where the pesticide residue is infrequently found or found on only a few foods. (Keep in mind that the prior example pertains to malathion, which is the most frequently occurring pesticide residue; see Table 2.) As mentioned previously, nearly 100% of the vinclozolin intake is from residues on strawberries. This resulted in a dietary intake of nearly 0.1 µg/day for the 14- to 16-year old male in 1989. If there had been another vinclozolin residue finding on strawberries at 5 ppm (half the EPA tolerance level), the intake would have been 1.7 µg/day. If there had been one finding at 5 ppm on lettuce (again, half the EPA tolerance level), the intake would increase to 15.4 µg/day, because of the much greater amount of lettuce consumed per day. If these findings had actually occurred, the daily intake would still have been less than 0.4% of the ADI.

## Summary and Conclusions

In recent enforcement monitoring conducted by FDA, no pesticide residues were found in more than half the food shipments sampled and analyzed. When residues were found, they were commonly present at low levels and rarely exceeded tolerances. Most violative residues were found in commodities for which a tolerance had not been set for the specific pesticide in question. These findings illustrate that pesticides are rarely used in a manner that results in residue levels that exceed tolerances.

FDA's Total Diet Study provides unique information for use in exposure assessment. The findings provide for determination of dietary intakes in foods as consumed and permit identification of trends and potential public health hazards. About 50 different pesticide residues are usually found. The most frequently found are the insecticide malathion and DDE, an environmentally persistent metabolite of DDT. The levels of most pesticide residues are orders of magnitude lower than residue tolerances applicable to raw agricultural commodities established by EPA. This may be attributed in part to the effects of food preparation, such as cooking and washing, on residue levels. Dietary intakes are well below established ADIs and RfDs, thus demonstrating the safety of the U.S. food supply.

The Total Diet Study will soon be revised to incorporate more recent food consumption information as well as additional pesticides, and will continue to serve as a final check on the effectiveness of the U.S. pesticide regulatory system.

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TABLE 1

Pesticide Intakes (µg/kg body wt/day) Found in Total Diet Analyses and Their ADIs/RfDs for 3 Age/Sex Groups in 1989

| Pesticide | Age/Sex Group | | | FAO/WHO ADI[b] | EPA RfD[b] |
|---|---|---|---|---|---|
| | 6-11 mo | 14-16 yr M[a] | 60-65 yr F[a] | | |
| Acephate | 0.0046 | 0.0033 | 0.0054 | 30 | 4 |
| Azinphos-methyl | 0.0017 | 0.0050 | 0.0039 | 2.5 | --[c] |
| BHC, alpha + beta | 0.0009 | 0.0014 | 0.0006 | --[c] | -- |
| BHC, gamma (lindane) | 0.0011 | 0.0020 | 0.0008 | 10 | 0.3 |
| Captan | 0.0129 | 0.0049 | 0.0160 | 100 | 130 |
| Carbaryl | 0.1004 | 0.0182 | 0.0343 | 10 | -- |
| Chlordane, total | 0.0001 | 0.0001 | 0.0001 | 0.5 | 0.06 |
| Chlorobenzilate | <0.0001 | 0.0001 | 0.0001 | 20 | 20 |
| Chlorothalonil | <0.0001 | <0.0001 | <0.0001 | 3[d] | 15 |
| Chlorpropham, total | 0.2700 | 0.4543 | 0.1496 | -- | 200[e] |
| Chlorpyrifos | 0.0131 | 0.0041 | 0.0043 | 10 | 3 |
| Chlorpyrifos-methyl | 0.0202 | 0.0236 | 0.0148 | 10 | -- |
| DCPA | 0.0012 | 0.0007 | 0.0013 | -- | 500 |
| DDT, total | 0.0287 | 0.0155 | 0.0079 | 20[f] | 0.5[e] |
| DEF | <0.0001 | 0.0001 | <0.0001 | -- | -- |
| Diazinon | 0.0031 | 0.0034 | 0.0017 | 2 | -- |
| Dicloran, total | 0.1382 | 0.0337 | 0.0832 | 30[e] | -- |
| Dicofol, total | 0.0118 | 0.0088 | 0.0096 | 25 | -- |
| Dieldrin | 0.0013 | 0.0015 | 0.0015 | 0.1[f] | 0.05 |
| Dimethoate | 0.0114 | 0.0022 | 0.0045 | 10[f] | 0.2 |
| Endosulfan, total | 0.0165 | 0.0088 | 0.0127 | 6[f] | 0.05[e] |
| Endrin | <0.0001 | <0.0001 | 0.0001 | 0.2 | 0.3 |
| Ethion, total | 0.0167 | 0.0060 | 0.0060 | 6[d,e] | 0.5[e] |
| Fenitrothion | 0.0008 | 0.0006 | 0.0009 | 5 | -- |
| Fenvalerate | 0.0137 | 0.0080 | 0.0132 | 20 | 25 |
| Folpet | 0.0004 | 0.0002 | 0.0005 | 10[d] | 100 |
| Fonofos | <0.0001 | 0.0001 | <0.0001 | -- | 2 |
| Heptachlor, total | 0.0007 | 0.0008 | 0.0006 | 0.5[f] | 0.5[e] |
| Hexachlorobenzene | 0.0007 | 0.0009 | 0.0005 | -- | 0.8 |
| Iprodione, total | 0.0045 | 0.0017 | 0.0026 | 300[e] | 40[e] |
| Linuron | 0.0004 | 0.0001 | 0.0002 | -- | 2 |
| Malathion | 0.1151 | 0.0924 | 0.0529 | 20 | 20 |
| Methamidophos | 0.0112 | 0.0116 | 0.0264 | 0.6 | 0.05 |
| Methomyl | 0.0094 | 0.0055 | 0.0148 | 30 | 25 |
| Methoxychlor, p,p' | <0.0001 | 0.0001 | 0.0001 | 100 | -- |
| Mevinphos, total | 0.0032 | 0.0020 | 0.0049 | 1.5[f] | -- |

| | | | | | |
|---|---|---|---|---|---|
| Omethoate | 0.0072 | 0.0017 | 0.0039 | 0.3 | -- |
| Parathion | 0.0091 | 0.0006 | 0.0011 | 5 | -- |
| Pentachlorophenol | 0.0013 | 0.0012 | 0.0015 | — | 30 |
| Permethrin, total | 0.0387 | 0.0364 | 0.0497 | 50 | 50 |
| Phosalone | 0.0104 | <0.0001 | 0.0001 | 6 | -- |
| Phosmet | 0.0019 | 0.0008 | 0.0009 | 20[f] | 20 |
| Phosphamidon | 0.0013 | 0.0039 | 0.0031 | 0.5[f] | -- |
| Pirimiphos-methyl | 0.0011 | 0.0013 | 0.0008 | 10 | 10 |
| Profenofos | 0.0001 | <0.0001 | 0.0001 | — | -- |
| Propargite | 0.5298 | 0.0613 | 0.0567 | 150 | 20 |
| Quintozene, total | 0.0005 | 0.0009 | 0.0002 | 7[f] | 3[e] |
| Sulfur | 0.0070 | 0.0018 | 0.0036 | -- | — |
| Tecnazene | <0.0001 | 0.0002 | <0.0001 | 10 | -- |
| Tetradifon | 0.0001 | <0.0001 | <0.0001 | — | — |
| Thiabendazole | 0.0854 | 0.0334 | 0.0581 | 300 | -- |
| Toxaphene | 0.0059 | 0.0087 | 0.0046 | -- | -- |
| Vinclozolin | 0.0039 | 0.0016 | 0.0048 | 70 | 25 |

[a]M = male, F = female.

[b]ADIs and RfDs are usually expressed as mg/kg body wt/day but are expressed here as µg/kg body wt/day for ease of comparison. The ADIs cited here reflect revisions made in 1988 and 1989. The RfDs cited here reflect April 3, 1990 EPA revisions, and are reprinted witl the permission of EPA.

[c]ADI or RfD not established.

[d]"Temporary" ADI.

[e]Parent chemical only.

[f]Includes other (related) chemicals.

Table 2. Frequency of occurrence of pesticides in Total Diet Study in 1989

| Pesticide[a] | Total No. of Findings[b] | Percent Occurrence |
|---|---|---|
| Malathion | 185 | 20 |
| DDT | 124 | 13 |
| Chlorpyrifos-methyl | 93 | 10 |
| Diazinon | 80 | 9 |
| Chlorpyrifos | 71 | 8 |
| Dieldrin | 62 | 7 |
| Methamidophos | 58 | 6 |
| Endosulfan | 51 | 5 |
| Chlorpropham | 48 | 5 |
| Hexachlorobenzene | 47 | 5 |
| Dicloran | 39 | 4 |
| Lindane | 34 | 4 |
| BHC, alpha & beta | 31 | 3 |
| Carbaryl[c] | 31 | 3 |
| Ethion | 28 | 3 |
| Quintozene | 27 | 3 |
| Acephate | 26 | 3 |
| Heptachlor | 26 | 3 |
| Dimethoate | 24 | 3 |
| Propargite | 23 | 2 |
| DCPA | 16 | 2 |
| Dicofol | 16 | 2 |
| Toxaphene | 14 | 1 |
| Omethoate | 13 | 1 |
| Parathion | 13 | 1 |
| Permethrin | 12 | 1 |
| Pirimiphos-methyl | 12 | 1 |
| Thiabendazole[d] | 11 | 1 |
| Methomyl[c] | 9 | 1 |

[a]Isomers, metabolites, and related compounds have not been listed separately; only the generic or "parent" pesticides from which they arise have been included.
[b]Based on 936 items.
[c]Reflects overall incidence; however, only 72 selected foods were analyzed for *N*-methyl carbamates.
[d]Analysis for propargite and thiabendazole began in FY89. Value reflects overall incidence; however, only 39 selected foods were analyzed for these particular sulfur-containing compounds.