June 6, 1999

Public Information and Records Integrity Branch
Information Resources and Services Division (7502C)
Office of Pesticide Programs
Environmental Protection Agency
401 M. Street, SW
Washington, D.C. 20460

RE: OPP-00593

To Whom It May Concern:

These comments are submitted on behalf of Consumers Union* in conjunction with the Natural Resources Defense Council, and address Office of Pesticide Programs Docket Number OPP-00593, a science policy paper entitled "Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern."

The agency's interim position states that if acute dietary risk associated with uses of a pesticide exceeds 99.9 percent of the PAD (Population Adjusted Reference Dose, or the acute RfD divided by any applicable FQPA safety factor), the agency –

> "…will conduct a sensitivity analysis to determine to what extent the estimated exposures at the high-end percentiles may be affected by unusually high food consumption or residue values."

The policy goes on to state that if one or a few residue levels or food consumption values "drive" exposure and risk estimates, the agency will assess whether the values are "representative." In a case where the agency finds a value to be "unrepresentative," we presume the agency intends to adjust the value or exclude the data point from the Monte Carlo analysis.

The interim policy statement clearly frames two related and important issues – what constitutes an "unusually high" food consumption or pesticide residue level? And when is such a level "representative?"

This interim policy could, if finalized and aggressively exploited, set the stage for purging food consumption and pesticide residue databases of high-end values. This

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would be an unacceptable result, which could seriously compromise the public-health goals of the FQPA. For obvious reasons, whether such values are "unusually" high or not, they will "drive" exposure and risk estimates because of simple mathematics. By the very nature of a Monte Carlo analysis, combinations of high-end food consumption and high-end residue values will occur at a frequency representing the likely odds of such occurrence in the real world. While such occurrences will account for a very small percentage of simulated eating day episodes, they nonetheless do occur and must therefore be taken into account by the agency.

"Unusually" High Values

According to the EPA, the need to assess whether a high-end food consumption value or residue is "unusual" arises if it accounts for a large percent of the risks faced by individuals that fall above the 99.9 percent level of their relevant PAD or RfD.

The agency's interim policy seems to accept the notion, often raised by pesticide industry and agricultural sector members of TRAC, that high-end Monte Carlo risk estimates are inflated because of outlier values or mistakes in data entry or coding that lead to gross overestimation of food consumption levels, pesticide residues, or both. If this were the case, the agency would indeed need a procedure to identify such data points so that they could be excluded or adjusted in a scientifically defensible manner.

Consumers Union has studied the available food intake and residue data extensively, and we have published our own analyses of the PDP data (see “Do You Know What You’re Eating?”, accessible at http://www.ecologic-ipm.com/findings.html#reports). For the reasons set forth below, we find no evidence of such an upward bias in the case of foods that account for the bulk of the diet of infants and children, and also for the vast majority of the risks associated with dietary exposure to organophosphate (OP) insecticides.

In elaborating on the lack of evidence for such biases, we here examine, first, the food consumption database used by the agency and most other organizations in carrying out acute dietary Monte Carlo analyses. Then, we assess the pesticide residue data used in Monte Carlo analyses.

Distribution of Food Consumption Values

We applaud the agency's use of the USDA's "Continuing Survey of Food Intake by Individuals," commonly referred to as the CSFII survey. It is the highest quality food consumption dataset available. We support the ongoing effort to update the data and to expand CSFII sample size and augment it with a special survey of consumption patterns among infants.

The draft science policy paper presents a clear description of the extensive quality control procedures that the USDA has developed over many years and now relies upon to assure that the consumption values in the CSFII are an accurate representation of the true distribution of actual eating patterns and habits. The key steps USDA uses to identify and correct any improperly entered or erroneously reported data are summarized on page 15 of the draft science policy paper. We concur with the conclusion reached by EPA and stated in the science policy paper:

> "Thus, the USDA CSFII data base has been properly evaluated and contains accurate and reliable consumption values that, by FQPA standards, are acceptable for use in OPP's assessment of human dietary exposure to pesticide residues."

Still, we are aware that other groups are warning the agency that implausible outlier values in the CSFII render Monte Carlo results "very unstable" at the high-end of the exposure and risk curves. To determine whether there is any validity to this claim, we assessed the distribution of actual reported food consumption levels in the 1994-1996 CSFII for one to five year olds.

There are 5,372 valid eating days in the CSFII for these age groups. Our analysis below focuses on children who ate apples, peaches, and pears, and who drank apple juice. The CSFII consumption values we assessed were provided by the Environmental Working Group (EWG). This consumption database was also drawn upon by EWG in their recent Monte Carlo assessment of acute azinphos methyl dietary risks. The results of this EWG Monte Carlo were transmitted to the agency on April 5, 1999 with a letter to Deputy Administrator Peter Robertson. The report is entitled "Children Are Overexposed to Guthion" (R. Wiles, T. Hettenbach, K. Cook, April 1999). Three key findings in the report state –

- "… 49,500 preschool children exceed EPA's acute reference dose for just one pesticide, Guthion, every day;"
- "Dietary exposure to Guthion alone, we find, presents more than twice the risk allowed in EPA's 'risk-cup' for all OPs;" and
- "Preschoolers at the 99.9th percentile of exposure are exposed to a dose that is 180 percent of the RfD."

The 5,372 valid eating days include records of 889 fresh apple eating day episodes by an individual child of known age and weight, 1,130 apple juice eating day episodes, 72 for peaches, and 97 for pears. Two eating days were reported for each child, typically over three days. Not all children consumed each of the four foods both days.

The apple, apple juice, peach, and pear consumption data analyzed below will be used in carrying out any one-chemical-at-a-time analysis, say of azinphos methyl or chlorpyrifos exposure and risk. The same data will be used to estimate cumulative dietary exposure and risk from all OPs found in these foods. In addition, efforts are underway to expand food consumption databases. As more recent data and additional samples are added to the 1994-1996 CSFII database, we would expect somewhat higher estimates of 99.9th level consumption, although we would expect only modest changes in mean, 95th and 99th levels of consumption.

The number of eating days simulated in a Monte Carlo run will affect distributions of risk somewhat, but we believe this effect will be minimal. The April 1999 azinphos methyl Monte Carlo carried out by EWG was based on the simulation of 5,000 eating days from each record in the data file, or 5,000 times 5,372 eating days. Clearly, the resulting 27 million simulated eating days, each with an accompanying calculation of the quantity of all residues consumed and attendant risks, produces a statistically dense distribution. For example, with 27 million simulated eating days, there will be 27,000 risk values over the 99.9th percentile of the distribution. This number is not just a statistical artifact, it is the number of children that would be exposed to residues over a safe level each day if EPA were to regulate to the 99.9th level. Some will argue this is “good enough” to meet the mandate of the FQPA but it clearly is not.

For the 5,372 CSFII eating days we calculated the grams of four key children’s foods consumed per kilogram of bodyweight – the best measure of the relative level of consumption across individuals on particular eating days. We then ranked the results according to this parameter and calculated a variety of descriptive statistics in order to characterize more fully the distribution of values.

For each food, we calculated the mean level of grams of food consumed per kilogram of bodyweight, the 95th percentile of consumption, the 99^{th,} and the 99.9th percentiles. The Appendix tables include the complete printout of all eating day episodes for the four foods assessed. Table 1 presents basic summary and descriptive statistics.

Table 1. Distribution of 1994-1996 CSFII Food Consumption Levels for Four Key Foods, Measured in Grams of Food per Kilogram of Bodyweight for Children Ages 1 to 5

	Apples	Apple Juice	Peaches	Pears
Maximum Value	26.7	136.7	11.5	29.2
99.9 Percentile	22.8	121.5	11.5	29.2
99 Percentile	18.0	78.1	11.1	18.3
95 Percentile	13.8	52.9	9.4	14.4
Mean	6.8	21.3	5.6	7.5
Minimum	0.2	0.8	1.1	0.6
Total Eating Days	889	1,130	72	97

Source: Compiled by Benbrook Consulting Services, based on 1994-1996 CSFII Consumption Data.

Table 1 shows clearly that there are no "odd-ball" outlier values in the CSFII food consumption survey data for these four major risk-driver foods consumed heavily by infants and children. In fact, there is only modest difference (2-fold to 6-fold differences for these four foods) between the 99.9th percentile of consumption and mean consumption. The tightness of the distribution is evident in Table 2, which presents ratios of various levels of consumption for these foods.

In the case of apples, there is only a 3.37 fold difference between the 99.9th percentile of consumption (22.8) and the mean level (6.8). Out of the 889 records (see Appendix Table 1), two eating episodes entailed consumption of over 400 grams in a day. A four-year old weighing 15.88 kilograms was responsible for the highest level of consumption per kilogram of bodyweight, 26.7 (the "Maximum" value noted in the table above); another four-year old child, the one at the 99.9th level of consumption, consumed 414 grams of apples. The child weighed 18.14 kilograms.

Table 2. Differences Between the Maximum, 99.9th, 99th, 95th and Mean Consumption Levels for Four Key Foods Consumed by Children Ages 1 to 5

	Apples	Apple Juice	Peaches	Pears
Ratio of --				
Maximum to 99.9	1.17	1.12	1	1
Maximum to 99	1.49	1.75	1.03	1.60
Maximum to 95	1.93	2.58	1.23	2.02
Maximum to Mean	3.95	6.43	2.06	3.90
99.9 to Mean	3.37	5.71	2.06	3.90
99 to Mean	2.66	3.67	1.99	2.45
95 to Mean	2.04	2.49	1.68	1.93
99.9 to 99	1.27	1.56	1.03	1.60
99.9 to 95	1.65	2.30	1.23	2.02
99 to 95	1.30	1.48	1.19	1.27

Source: Compiled by Benbrook Consulting Services, based on 1994-1996 CSFII Consumption Data.

This level of consumption reflects 3 medium sized apples, since USDA estimates that an average apple weighs 138 grams (see Table 3 for more on average weights of individual food items). While a high level, most parents are aware that their children eat certain favorite foods at various stages of growing up in comparable or even greater quantities. Kids that like apples might consume one apple at breakfast, a part of one for lunch and dinner, and other portions for snacks two or three times during the day. Sometimes children who are teething work on an apple for most of their waking hours. The child that consumed the third highest level ate 212 grams – 1.5 apples -- as did the child at the 99th level of consumption, a two-year old weighing 11.79 kilograms.

There were four children, all about 10 kilograms in weight, who consumed one apple and fell at the 95th level of consumption, or 13.8 grams per kilogram of bodyweight. Regrettably, 95 out of 100 kids ate less than an apple a day, a level of consumption no one would label as shockingly high.

Are the top two records outliers because three apples a day were consumed? We think not, they just reflect high-end but realistic consumption. Another five-year old child consumed three apples, but weighed almost twice as much and so fell further down the ranking based on grams consumed per kilogram of bodyweight. A two-year child just below the 99^{th} level of consumption ate 318 grams, or two and one-third apples. So while the amounts eaten by the top two children in the ranking were exceptional, the amount per kilogram of bodyweight was not very different from the heavy eaters among both younger and older children. The child at the 99.9^{th} level of consumption ate only 1.65 times as much apples per kilogram of bodyweight as the four children at the 95^{th} level.

In the case of apple juice (see Appendix Table 2), the number of grams consumed is much higher but again, the distribution is remarkably tight. There is just a 2.3 fold difference between the 99.9^{th} level of consumption and the 95^{th} level, and only a 5.7 fold difference between the 99.9^{th} level and the mean; the 99^{th} differs from the mean by 3.67, and the 95^{th} is just 2.5 times the mean.

In the case of peaches and pears (see Appendix Tables 3 and 4), the distributions are much tighter, reflecting in part the smaller sample size and the procedures USDA employs to eliminate values that appear excessive or implausible relative to the rest of the values in the distribution. The fewer samples, the more likely a high-end value will appear excessive relative to the rest of the distribution. In the case of peaches and pears, the 99.9^{th} level of consumption is the maximum value, and it exceeds the mean by 2.06 and 3.9 fold respectively. The other important consequence of low sample size is the likelihood rises that the 99.9^{th} level of consumption will be significantly underestimated – perhaps by an order of magnitude based on a review of these four foods.

Are High-End Consumption Values Plausible?

To gain further perspective on whether the high-end consumption values in the CSFII database are plausible, we compared the grams of food reported as eaten to the caloric needs of children between 1 and 5. For the four foods studied, Table 3 shows the size of a "common edible portion" in grams and common terms (by "common term," we mean one apple or a cup of apple juice), as well as the kilocalories associated with a common portion. Edible portion data are from USDA's publication *Nutritive Value of Foods* (USDA/HNIS. Home and Garden Bulletin Number 72, June 1991).

Table 3. Common One-time Serving Portions and Kilocalories for Four Key Children's Foods			
Food	**Common Edible Portion (grams)**	**Common Portion (description)**	**Kcals**
Apples, raw unpeeled	138	1 apple	80
Apple Juice	248	1 cup	115
Pears	166	1 pear	100
Peaches	87	1 peach	35
Source: *Nutritive Value of Foods*, USDA/HNIS, 1991.			

Table 4 then contrasts common edible portions to the maximum portions reported in the CSFII for one, two and four-year olds. The top third of Table 4 covers one-year olds; the middle third, 2-year olds, and the bottom third, four-year olds. The maximum consumption values by age group and food are all from the 1994-1996 CSFII datafile discussed above.

For the three fruits, even the maximum amount consumed – about three apples by a four-year old – constitutes only 18 percent of that child's likely daily caloric need. The high-end peach consumer received only 7 percent of caloric need, and for pears, 14 percent.

Table 4. Maximum CSFII Food Consumption Values in Perspective: Four Foods and Three Age Groups				
Food	**Common Edible Portion (grams)**	**Maximum Consumption in CSFII (grams)**	**Maximum Consumption (descriptive)**	**% of Daily Kcal Needs at Maximum Consumption**
One Year Olds				
Apples, raw unpeeled	138	212	1.5 apples	12%
Apple Juice	248	1,488	6 cups	69%
Pears	166	166	1 pear	10%
Peaches	87	177	2 peaches	7%
Two Year Olds				
Apples, raw unpeeled	138	318	2.3 apples	15%
Apple Juice	248	2,232	9 cups	86%
Pears	166	278	1.7 pears	14%
Peaches	87	157	1.8 peaches	5.3%
Four Year Olds				
Apples, raw unpeeled	138	424	3.1 apples	18%
Apple Juice	248	2,480	10 cups	82%
Pears	166	332	2 pears	14%
Peaches	87	157	1.8 peaches	4.5%
Source: Compiled by Benbrook Consulting Services, based on food consumption data from the 1994-1996 CSFII.				

Apple juice, on the pother hand, accounted for as much as 86 percent of caloric need. In all likelihood, children consuming this much juice exceeded their recommended caloric intake on days when 6 to 10 cups of apple juice were consumed. Such significant consumption probably occurred in unusual circumstances, like a summer picnic or birthday party when the child was very active, outside in warm temperatures.

In summary, we are confident that when the consumption values for other commonly consumed commodities are subjected to the same sort of analysis, the results will be comparable. The agency and USDA can readily confirm this prediction by issuing a ranking and summary of reported food consumption episodes, for the 20 or so major foods making up most of the diet of infants and children. This could be done each time a new set of data is released through the CSFII.

The agency's science policy paper notes that some foods are reported as eaten by very few children. First, it is important to note that these values will have a modest impact on the total distribution of exposure and risks for any widely used OP, and even less of an impact when EPA carries out its cumulative acute dietary OP Monte Carlo analysis. This is because the food eating episodes will be selected infrequently, and several of these will have no or low levels of residues associated with them, and hence will contribute little if any toward exposure and risk totals.

We believe the USDA's statistical procedures are catching and truncating any implausible values, and that the distribution of consumption levels per kilogram of bodyweight will be tight in cases with few reporting eating episodes. But to allay fears that a truly unusual value in a rarely consumed food might skew upward an estimate of risk, even for a very few individual eating day risk estimates, we concur that the agency should put in place an empirical filter to trigger an assessment of such unusual cases. We recommend further assessment of high-end consumption values if two conditions are met. First, one of these two triggers should apply –

- the 99th level of consumption exceeds the mean by six-fold or more, or
- the 95th level of consumption exceeds the mean by four-fold or more.

Then, the EPA should require an affirmative judgement from an expert panel of dieticians and food consumption specialists that high-end consumption levels meeting one or both of the above triggers are, in fact, implausible. One obvious set of cases where such levels would be plausible, and should not be altered, is a food typically served and consumed as a garnish in relatively low quantities – leading to a relatively large number of low-consumption episodes (and hence a low mean) -- which some children eat as a main course, perhaps in an ethnic dish or seasonal favorite of a family.

Distribution of Pesticide Residue Levels

The USDA Pesticide Data Program provides the highest quality, most up to date residue data covering the foods most heavily consumed by infants and children. For foods tested by PDP, even if sampled in just one year, PDP data should be used as the primary dataset in carrying out Monte Carlo assessments. The advantages of the PDP – reflecting food as eaten, after storage, washing and preparation – outweigh the disadvantages of smaller sample sizes than what might be accessible by combining several years of FDA surveillance monitoring data, or other data sources of more debatable relevance and quality.

Dietary exposure and risks from foods sampled by PDP will almost certainly dwarf risks from foods that children eat less often. Among dietary exposures, residues in drinking water and liquids made from contaminated water, or certain juices could account for comparable, and in some cases, greater levels of dietary exposure in contrast to foods sampled by the PDP. For this reason, a special sampling should be carried out as soon as possible covering high consumption liquids including common soft-drinks, fruit juice based drinks (other than the already tested apple, grape and orange juices), frozen and packaged snack drinks.

The larger the PDP dataset for a given food, the greater the confidence that can be placed in the data. For this reason, if the condition stated below is met, we support the merging of up to three years of PDP data for a single food. The condition is that data should not be merged if there were substantial changes in pesticide use patterns – acres treated, rates of application, or timing of application between years. We suggest a "substantial equivalency test" -- accept no more than a 25 percent change from one year to the next in any of these three indicators of pesticide use patterns. USDA pesticide use data, augmented by reports from extension specialists in the field for the years when USDA does not collect fruit or vegetable data, can be used to apply this test in years when USDA does not collect fruit or vegetable use data.

After discussing the distribution of composite PDP residue levels, we address two major benefits of decompositing positive PDP samples to sets of individual sample values. Decompositing will both markedly expand the number of positives within a dataset, and it will more accurately reflect the true distribution of residue values at the upper-end of the distribution of residue values. Both changes will provide a sounder scientific footing for subsequent acute dietary Monte Carlo analyses.

The Distribution of Pesticide Residue Levels in PDP Data

Just as in the case of food consumption values, some allege that a few grossly exaggerated pesticide residue values are driving high-end risk outcomes in Monte Carlo analyses. This assertion is nonsense. We analyzed 53 food-pesticide combinations in the 1997 PDP sampling that account for significant exposures, including some active ingredients found in over 50 percent of samples tested (others were found in less than 10 percent). For each, we assessed the same descriptive statistics of the distribution of residue values as analyzed in the case of CSFII food consumption values.

Table 5. Key Indicators of the Distribution of Pesticide Residues Found in 11 Foods Sampled by the Pesticide Data Program in 1997									
Food	**Active Ingredient**	**# of Samples**	**# of Positives**	**Maximum Positive Residue**	**99.9th Percent of Positives**	**99th Percent of Positives**	**95th Percent of Positives**	**Mean of Positives**	**Minimum Positive**
apple juice	azinphos-methyl	683	43	0.062	0.062	0.062	0.038	0.022	0.010
apple juice	carbaryl	683	168	0.167	0.167	0.110	0.060	0.019	0.007
apple juice	dimethoate	683	184	0.054	0.054	0.041	0.016	0.009	0.003
apple juice	diphenylamine (DPA)	668	57	0.150	0.150	0.150	0.086	0.034	0.013
apple juice	methamidophos	683	14	0.005	0.005	0.005	0.005	0.004	0.002
apple juice	omethoate	683	56	0.015	0.015	0.015	0.015	0.011	0.007
apple juice	thiabendazole	677	214	0.930	0.930	0.760	0.510	0.203	0.015
green beans	acephate	669	306	0.700	0.700	0.470	0.270	0.074	0.003
green beans	carbaryl	698	75	0.600	0.600	0.380	0.290	0.074	0.007
green beans	methamidophos	679	304	0.170	0.170	0.120	0.082	0.027	0.002
green beans	parathion-methyl	707	33	0.380	0.380	0.380	0.230	0.048	0.003
green beans	vinclozolin	684	123	0.230	0.230	0.210	0.096	0.030	0.005
orange juice	carbaryl	692	24	0.031	0.031	0.031	0.013	0.011	0.010
orange juice	ethion	692	69	0.006	0.006	0.004	0.003	0.002	0.002
orange juice	thiabendazole	677	44	0.340	0.340	0.340	0.150	0.076	0.042
peaches	carbaryl	739	80	0.484	0.484	0.400	0.220	0.079	0.010
pears	azinphos-methyl	702	479	0.990	0.990	0.620	0.310	0.085	0.010
pears	captan	683	64	2.200	2.200	1.400	0.980	0.233	0.010
pears	carbaryl	708	42	0.810	0.810	0.810	0.240	0.061	0.007
pears	diazinon	708	24	0.094	0.094	0.094	0.048	0.014	0.003
pears	diphenylamine (DPA)	693	158	1.800	1.800	1.600	0.420	0.109	0.013
pears	o-phenylphenol	614	154	11.000	11.000	9.800	3.800	0.804	0.005
pears	parathion-methyl	708	37	0.079	0.079	0.079	0.064	0.018	0.003
pears	phosmet	613	114	0.720	0.720	0.630	0.300	0.099	0.008
pears	thiabendazole	695	467	4.700	4.700	3.100	1.800	0.559	0.015
soybean, grain	chlorpyrifos	157	126	0.195	0.195	0.107	0.047	0.014	0.003
soybean, grain	malathion	159	53	0.325	0.325	0.048	0.026	0.014	0.003
spinach, canned	permethrin	168	141	5.000	5.000	4.800	3.300	1.187	0.067
spinach, fresh	DDE	512	212	0.110	0.110	0.057	0.044	0.016	0.005

spinach, fresh	dimethoate	501	32	1.900	1.900	1.900	0.340	0.141	0.003
spinach, fresh	endosulfan sulfate	512	45	0.940	0.940	0.940	0.280	0.070	0.005
spinach, fresh	methomyl	512	51	1.500	1.500	1.200	0.530	0.178	0.020
spinach, fresh	omethoate	512	65	0.760	0.760	0.640	0.380	0.099	0.007
spinach, fresh	permethrin	512	271	9.200	9.200	7.700	4.700	1.574	0.017
sweet potatoes	chlorpyrifos	695	76	0.037	0.037	0.029	0.018	0.009	0.005
sweet potatoes	dicloran	679	388	1.700	1.700	1.200	0.800	0.291	0.010
sweet potatoes	phosmet	671	38	0.420	0.420	0.420	0.220	0.101	0.010
tomatoes	azinphos-methyl	705	10	0.710	0.710	0.710	0.710	0.095	0.013
tomatoes	chlorothalonil	708	54	1.700	1.700	0.630	0.420	0.110	0.008
tomatoes	chlorpyrifos	707	92	0.310	0.310	0.300	0.110	0.033	0.005
tomatoes	endosulfan I	709	121	0.330	0.330	0.057	0.035	0.012	0.003
tomatoes	endosulfan II	722	158	0.100	0.100	0.068	0.036	0.014	0.005
tomatoes	endosulfan sulfate	722	140	0.098	0.098	0.054	0.025	0.012	0.005
tomatoes	methamidophos	710	217	0.350	0.350	0.290	0.140	0.040	0.002
tomatoes	permethrin	707	80	0.173	0.173	0.160	0.130	0.065	0.017
wheat grain	chlorpyrifos-methyl	622	346	1.796	1.796	1.100	0.423	0.106	0.002
wheat grain	malathion	623	425	7.550	7.550	4.756	0.864	0.213	0.005
winter squash, fresh	chlorothalonil	405	27	0.230	0.230	0.230	0.200	0.056	0.008
winter squash, fresh	endosulfan I	440	32	0.048	0.048	0.048	0.035	0.012	0.003
winter squash, fresh	endosulfan II	440	23	0.015	0.015	0.015	0.012	0.010	0.005
winter squash, fresh	endosulfan sulfate	440	111	0.086	0.086	0.071	0.033	0.017	0.005
winter squash, fresh	methamidophos	440	16	0.039	0.039	0.039	0.021	0.009	0.002
winter squash, frozen	dieldrin	91	67	0.100	0.100	0.096	0.072	0.028	0.003

Source: Compiled by Benbrook Consulting Services, based on PDP program datafile from the Agricultural Marketing Services, USDA.

Table 5 provides summary statistics on the 53 food-pesticide combinations. It shows the number of samples, number of positives, the maximum residue level, the 99.9th, 99th, and 95th residue levels, the mean of the positives and the minimum positive (usually the limit of detection). There were no cases with over 500 positive samples, and hence the 99.9th percentile of the distribution of values in all cases is also the maximum value. (This will change when PDP data are combined over two to three years and decomposited; the 99.9th level residue might become the third or fourth, or tenth from the top value – likely not too far from the current maximum for a PDP composite sample).

Table 6. Ratios Showing the Differences Between Selected Points in the Distribution of Pesticide Residue Levels: Positive Residues Found in 11 Commodities Sampled by the Pesticide Data Program in 1997

Food	Active Ingredient	Ratio of 99.9 to Mean	Ratio of 99 to Mean	Ratio of 95 to Mean	Ratio of 99.9 to 95	Ratio of 99 to 95	Ratio of Mean to Min
apple juice	azinphos-methyl	2.848	2.848	1.746	1.632	1.632	2.177
apple juice	carbaryl	8.718	5.743	3.132	2.783	1.833	2.736
apple juice	dimethoate	6.096	4.628	1.806	3.375	2.563	2.953
apple juice	diphenylamine (DPA)	4.419	4.419	2.533	1.744	1.744	2.611
apple juice	methamidophos	1.346	1.346	1.346	1.000	1.000	1.857
apple juice	omethoate	1.382	1.382	1.382	1.000	1.000	1.551
apple juice	thiabendazole	4.588	3.750	2.516	1.824	1.490	13.513
green beans	acephate	9.460	6.352	3.649	2.593	1.741	24.666
green beans	carbaryl	8.105	5.133	3.918	2.069	1.310	10.575
green beans	methamidophos	6.280	4.433	3.029	2.073	1.463	13.535
green beans	parathion-methyl	7.842	7.842	4.747	1.652	1.652	16.152
green beans	vinclozolin	7.694	7.025	3.211	2.396	2.188	5.979
orange juice	carbaryl	2.725	2.725	1.143	2.385	2.385	1.138
orange juice	ethion	2.706	1.804	1.353	2.000	1.333	1.109
orange juice	thiabendazole	4.467	4.467	1.971	2.267	2.267	1.812
peaches	carbaryl	6.091	5.034	2.769	2.200	1.818	7.946
pears	azinphos-methyl	11.677	7.313	3.657	3.194	2.000	8.478
pears	captan	9.446	6.011	4.208	2.245	1.429	23.289
pears	carbaryl	13.248	13.248	3.925	3.375	3.375	8.735
pears	diazinon	6.635	6.635	3.388	1.958	1.958	4.722
pears	diphenylamine (DPA)	16.545	14.707	3.861	4.286	3.810	8.369
pears	o-phenylphenol	13.675	12.183	4.724	2.895	2.579	160.875
pears	parathion-methyl	4.469	4.469	3.621	1.234	1.234	5.892
pears	phosmet	7.264	6.356	3.027	2.400	2.100	12.390
pears	thiabendazole	8.404	5.543	3.219	2.611	1.722	37.284
soybean, grain	chlorpyrifos	13.575	7.449	3.272	4.149	2.277	4.788
soybean, grain	malathion	24.057	3.553	1.925	12.500	1.846	4.503
spinach, canned	permethrin	4.211	4.042	2.779	1.515	1.455	17.723
spinach, fresh	DDE	6.703	3.473	2.681	2.500	1.295	3.282
spinach, fresh	dimethoate	13.448	13.448	2.407	5.588	5.588	47.094
spinach, fresh	endosulfan sulfate	13.429	13.429	4.000	3.357	3.357	14.000
spinach, fresh	methomyl	8.417	6.733	2.974	2.830	2.264	8.911
spinach, fresh	omethoate	7.706	6.489	3.853	2.000	1.684	14.090
spinach, fresh	permethrin	5.846	4.893	2.987	1.957	1.638	92.573
sweet potatoes	chlorpyrifos	4.178	3.275	2.033	2.056	1.611	1.771
sweet potatoes	dicloran	5.845	4.126	2.751	2.125	1.500	29.084

sweet potatoes	phosmet	4.169	4.169	2.184	1.909	1.909	10.074
tomatoes	azinphos-methyl	7.505	7.505	7.505	1.000	1.000	7.277
tomatoes	chlorothalonil	15.452	5.726	3.818	4.048	1.500	13.752
tomatoes	chlorpyrifos	9.299	8.999	3.300	2.818	2.727	6.667
tomatoes	endosulfan I	26.496	4.577	2.810	9.429	1.629	4.152
tomatoes	endosulfan II	7.291	4.958	2.625	2.778	1.889	2.743
tomatoes	endosulfan sulfate	8.104	4.465	2.067	3.920	2.160	2.419
tomatoes	methamidophos	8.849	7.332	3.540	2.500	2.071	19.776
tomatoes	permethrin	2.646	2.447	1.989	1.331	1.231	3.846
wheat grain	chlorpyrifos-methyl	16.921	10.364	3.985	4.246	2.600	53.071
wheat grain	malathion	35.388	22.292	4.050	8.738	5.505	42.670
winter squash, fresh	chlorothalonil	4.132	4.132	3.593	1.150	1.150	6.958
winter squash, fresh	endosulfan I	4.021	4.021	2.932	1.371	1.371	3.979
winter squash, fresh	endosulfan II	1.438	1.438	1.150	1.250	1.250	2.087
winter squash, fresh	endosulfan sulfate	5.143	4.246	1.974	2.606	2.152	3.344
winter squash, fresh	methamidophos	4.333	4.333	2.333	1.857	1.857	4.500
winter squash, frozen	dieldrin	3.633	3.488	2.616	1.389	1.333	9.174

Source: Compiled by Benbrook Consulting Services, based on PDP program datafile from the Agricultural Marketing Services, USDA.

The data in Table 5 were used to produce Table 6, which shows the ratios of the 99.9th level to the mean, the 99th to the mean, the 95th to the mean, the 99th to the 95th, and the mean to the minimum. Table 6 was, in turn, used as the source of Table 7 below, which summarizes the distribution of residue levels in these 53 food-pesticide combinations. The cells in Table 7 report the number of food-pesticide combinations that fall within certain ranges in ratio values. The first row of data refer to the ratio of the 99.9th percentile level of residues to the mean residue; the second row of data reflects the ratio of the 95th percentile residue level to the mean. There were, for example, 5 food-pesticide combinations in which the ratio of the 99.9th level residue to the mean residue fell between 2 and 4.

Table 7. Number of Ratio Values Falling within Certain Ranges for 53 Food-Pesticide Combinations Tested in 1997 by the Pesticide Data Program: Numbers in Cells Equal Number of Food-Pesticide Cases

	Number of Cases with Ratio Values that are --						
	< 2	2 to 4	4 to 6	6 to 8	8 to 12	> 12	Total
Ratio of --							
99.9th to the Mean	3	5	13	11	10	11	53
95 to Mean	11	36	5	1	0	0	53

Source: Compiled by Benbrook Consulting Services, based on PDP program datafile from the Agricultural Marketing Services, USDA.

There are two major reasons why there are 21 food-chemical combinations with 99.9th to mean ratios above 8 – an expected finding. First, the 99.9th percentile residue is in all cases actually the maximum level found, because there are far fewer than 1,000 positive samples in the dataset.

Second, the PDP strives for very low limits of detection, and hence for most food-pesticide combinations, the lowest residue detected is in the 0.01 ppm to 0.002 ppm range – very low levels indeed. In cases where most of the residues are found near or at the limit of detection, the mean residue will also be low. A review of Table 4 confirms that there are 21 cases out of 53 where the mean residue exceeds the minimum by less than five-fold – evidence of a distribution of residues dominated by low levels. In such cases, the relative few higher-end residues will produce large ratio values relative to the mean.

To further drive home the point that PDP residue values are, for the most part, tightly distributed, we also present in the appendix a complete printout of all 8,108 positive samples in the 1996 PDP, organized by food tested, and then by active ingredient and country of origin, ranked from the maximum residue level found to the minimum. A review of the high-end residues throughout Appendix Table 5 supports the basic conclusion that there are no outlier values. In the few cases where the ratio value is greater than 10 between the 99th and mean levels, it is almost always because there were very few positives found, or many positives at a relatively low level, and just a few high values. In such cases, the high-end residues no doubt reflect a unique set of weather and application circumstances, or a relatively short period between harvest and consumption. But such values are clearly in the food supply and must remain unadjusted in the dataset because unusual circumstances do occur in the real world.

So what might constitute an outlier PDP composite pesticide residue value that reflects, for example gross misuse or error? Given the design of the program, we do not believe there are any circumstances that would lead to a composite residue level that does not, in fact represent actual levels of residues in the food supply. While some very high residues may result from illegal pesticide use, the FQPA makes no distinction between residues from legal and illegal uses.

Based on the clear mandate of the FQPA, we urge EPA to include all such exposures in its cumulative risk assessments. Such cases will contribute relatively infrequently to exposures among children exceeding their PAD or RfD on a given day, but still may warrant attention as the agency sorts its way through risk mitigation options for a given set of active ingredients and/or foods contributing excessively to acceptable exposures and risks.

Decompositing – A Valuable Step Toward More Realistic Residue Levels

The EPA and USDA are refining a method to decomposite PDP residues to better reflect the actual distribution of residues in the individual pieces of fruit or vegetable consumed. PDP samples are a composite of about five pounds of an item – about 20 apples, or 400 grapes, for example. Decompositing is based upon additional testing done to assess residues in individual samples, as well as the composite they become part of. The process computes, in the case of apples, 20 individual sample residue levels, some higher than the mean, others lower and some below the limit of detection, such that the composite of the individual samples would result in the residue level found in the composite.

Both the Ministry of Agriculture, Fisheries, and Food in Great Britain and the USDA PDP have recently conducted pilot projects to assess the likely distributional patterns of individual samples within a composite for specific foods. We support this process and are confident the agencies will reach concurrence on a decompositing protocol that produces a realistic distribution of residue values in individual samples.

Given the USDA-EPA commitment to creating the soundest scientific footing as possible for acute dietary risk assessment, it is imperative for the agencies to complete the process of decompositing PDP data, at least for the major foods tested by PDP to date that are typically eaten as single items. Once an acceptable decompositing protocol is in place, it will add little expense to the PDP to report annually the results of sampling both based on composite testing and computed individual samples.

In summary, we strongly oppose any unscientific "doctoring" of the CSFII or PDP databases supporting the agency's Monte Carlo acute dietary risk assessments. As we have shown, the quality control procedures used by the USDA in developing these data resources have produced very high quality data, at significant expense to the taxpayer. It would therefore be unconscionable for the agency to acquiesce to proposals that are intended to make high-end exposure estimates "go away" because they deviate too greatly from what some want to label as "usual" or "representative" patterns of exposure and risk. It is precisely children with high but predictable “normal” exposure who are at risk and whom the FQPA is designed to better protect.

How to Apply the 99.9th Percentile Goal?

The agency seeks comments on whether and how to apply the 99.9th level of protection it its implementation of the FQPA. In the case of acute dietary risk assessment, the agency proposes to regulate exposures to each chemical down to the level at which the individual at the 99.9th level of the risk distribution meets his or her personal PAD or RfD for that chemical.

We strongly object to this goal. It totally ignores the cumulative exposure mandate of the FQPA. Regulating any of the major OPs to the 99.9th level, even if met, would leave some 25,000 children over their RfD on a daily basis from exposures to that single OP. Given the likelihood of dietary exposures to 3 to 8 OPs in any given day, this approach will fall far short of the FQPA's mandate.

Given the gaps in EPA's knowledge of residues in food and water, and even more spotty data on other exposure pathways, we are certain that there will be a substantially greater number of children over their RfD on any given day, and many by a wide margin, if the goal of regulation remains just reducing exposures to the 99.9th level one chemical at a time. This policy must be rejected.

The agency should strive to assure, as an initial step toward the FQPA's risk reduction mandate, that dietary exposures are reduced such that 100 percent of children eating day episodes result in exposures well within the allowable risk cup for any individual chemical. While further risk reducing steps may later be needed to meet the cumulative risk reduction goal, the above initial goal will clearly focus attention on the high-risk foods and encourage growers and the industry to take far more seriously the need for change in pest management systems.

Instead of applying the 99.9th percentile goal to levels in the distribution of risks to one chemical at a time, the agency should instead just apply the 99.9th percentile goal to the distribution of risk estimates produced as a result of cumulative acute dietary risk assessments. If the 99.9th percentile goal were applied in this way, the agency would be able to argue forcefully that it had relied on the best data and risk assessment science available to assure that 99.9th percentile of the eating day episodes for all infants and children result in total exposures below the level of concern.

Applying the 99.9th percentile goal in this fashion is the most defensible approach statistically in the case of the OPs. The cumulative OP risk assessment will no doubt draw on a large Monte Carlo run, entailing millions of simulated child eating days, drawing on a very large residue database, especially after PDP and other composite data is decomposited. The enormity of this dataset, and the richness of the food consumption and residue data underlying it, will produce a much more realistic and reliable distribution of residues than ever before possible.

As more accurate and complete exposure and toxicology data are generated, and more refined risk assessment methods emerge, the agency can and should annually update all risk-cup decisions and exposure-risk estimates. With the updated numbers, the agency should first assure that the "reasonable certainty of no harm" standard is being met, or acceptable progress is being made toward its attainment within a reasonably short transition period. If clearly articulated risk reduction targets are not met, the agency should impose appropriate additional risk mitigation measures, where and how it sees necessary.

Second, the agency should periodically revisit the portions of the risk-cup allotted to, or taken up by different crops and routes of exposure. On the basis of updated data, the agency should confirm that the distributions of the risk cup represent sound decisions reflecting the mutual interests and needs of growers, the food industry, and consumers. If the agency cannot offer such confirmation, it should take appropriate steps to gradually adjust the allocation of the risk cup in ways that promote the general welfare without eroding progress made toward the achievement of the FQPA's basic mandate – a farming and food system that routinely delivers food for all free of unsafe pesticide residue levels.

Answers to Specific Questions and Other Comments

Question 1 asks about when a Monte Carlo exposure and risk estimate becomes "so uncertain" that the agency should not use it in decision-making?

We support assuring that the underlying food consumption and residue databases are themselves sound prior to their incorporation in a Monte Carlo. By avoiding the "garbage in" syndrome, the agency will not have to fight wasteful battles over the fate of "garbage out."

We have suggested concrete criteria the agency could apply in assessing whether a food consumption value is an outlier –

- the 99^{th} level of consumption exceeds the mean by six-fold or more, or
- the 95^{th} level of consumption exceeds the mean by four-fold or more.

In addition, there would need to be an affirmative judgement from an expert panel of dieticians and food consumption specialists that high-end consumption levels meeting one or both of the above triggers are, in fact, implausible.

Question 2 asks about what level the agency should establish its threshold for concern? We have answered this question clearly in the above narrative. In summary, when carrying out one-chemical-at-a-time Monte Carlos, the goal should be 100 percent of child eating days should be well below the portion of the allowable PAD or RfD allotted to dietary exposures and risks.

When carrying out a cumulative dietary exposure and risk assessment, like the one that must be done on all food uses of all OPs, we would support adopting the 99.9th percentile in the resulting cumulative risk distribution as the level of concern, assuming the agency has set aside a prudent portion of the cumulative PAD or RfD for other routes of exposure, and to help cover data gaps and surprises.

If that level is met, it is unlikely more than a few children would experience eating days leading to exposures over their personal PAD or RfD, since this exposure target-level would be based on some percent of the child's total allowable PA or RfD. The only children that might be over on a given day would be those at the very highest end of the dietary risk distribution, and at the highest end of risks from other routes of exposure – a rare event indeed (but not implausible).

Question 3 – the agency should not accept anything lower than 99.9^{th} percentile of the distribution of risks in a cumulative assessment as its goal; hence no further response is needed to this question.

Question 4 asks about various sliding scales to adjust the strictness of regulatory interventions as a function of several variables. This is a set of ideas perhaps 50 years ahead of its time. After a full and complete set of endocrine system, immune system, and developmental toxicity tests have been developed and verified, and carried out on all pesticides used on food, it might be useful to revisit this suggestion. Then, many years of expert advisory panels, at least one NAS review, and many consensus building activities among stakeholders will be required to forge agreement on how to rank health impacts on a relative scale, a necessary step to implement this idea. As sound as this suggestion might seem conceptually, the considerable technical and political challenges inherent in implementing it would set back attainment of FQPA goals by at least 20 years, and for this reason alone, the suggestion should be rejected.

Question 5 asks how to identify outliers, answers have already been provided.

Question 6 is deeply disturbing and implies that the agency will doctor a dataset simply because it provides an uncomfortable result that requires the agency to take action, i.e. impose regulations. The agency should expect very few food-pesticide combinations to account for the lion's share of risk. If the agency simply defines all high-end risk estimates as outliers, the FQPA will have no beneficial, health-protective impact.

Question 7 asks about trying to incorporate variability in human sensitivity to toxic effects.

Yes, the agency must take steps to increase the protection accorded to vulnerable populations. This might take the form of an added variable in a Monte Carlo model to assure adequate margins of safety for certain special populations, or among vulnerable people who are heavy consumers of certain fresh fruits and vegetables, or ethnic foods.

There will still be cases when the agency knows some people -- those who are chemically sensitive or genetically vulnerable because of a rare disorder – may not be fully protected. In such cases, the agency will need to augment prudence in setting PADs and RfDs with additional, targeted assistance to certain individuals. The goal should be to help them, to the extent possible, avoid foods and circumstances where they might be exposed to a level of pesticides triggering adverse health consequences.

Thank you for the opportunity to provide these comments. Please count all the data in the appendix tables as an integral part of these comments.

Sincerely,

Edward Groth III — Consumers Union

Lawrie Mott — Natural Resources Defense Council