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Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

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PESTICIDES

Food Consumption Data of Little Value to Estimate Some Exposures

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GAO

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Resources, Community, and
Economic Development Division

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May 22, 1991

The Honorable John D. Dingell
Chairman, Subcommittee on
Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

Publicized food poisonings from improperly used pesticides and health risks from pesticides once considered acceptable for food use contribute to a continuing concern about pesticide-contaminated food. To establish safe levels of pesticide residues in or on food, the Environmental Protection Agency (EPA) estimates dietary exposure to pesticide residues using data from the U.S. Department of Agriculture's (USDA) Nationwide Food Consumption Survey, conducted every 10 years. However, for budgetary reasons the sample size of the most recent survey (1987-88) was about one-third the sample size of the 1977-78 survey. Because of this reduced sample size, as well as the survey's low response rate, data were obtained from about one-third as many individuals—10,172 individuals, as opposed to 30,770.

The survey's low response rate (below 34 percent) could result in exposure estimates that are not representative of the U.S. population. This is because the survey data may not be weighted or otherwise corrected to account fully for eating patterns of nonrespondents that differ systematically from those of respondents. An independent expert panel reviewed the effect of nonresponse on the survey data and concluded that the data should not be used unless the greatest caution is employed. This and other sources of survey error are discussed in an upcoming report (GAO/RCED-91-117), which will focus on the methodological soundness of the survey's design and implementation.

Concerned about the reduced sample size and about the general reliability of EPA's exposure estimates for establishing safe pesticide residue levels, you requested that we examine (1) the adequacy of USDA's 1987-88 survey data for EPA's future exposure estimates; (2) the adequacy of EPA's current exposure estimates, based on the 1977-78 survey data; and (3) EPA's involvement in designing the 1987-88 survey.

Results in Brief

It is very unlikely that the data obtained from the reduced sample size used in USDA's 1987-88 food consumption survey are adequate for EPA's use in calculating reliable exposure estimates for such subpopulations as nursing infants, pregnant women, and other groups in which only a small number of people were surveyed. Although the data may be adequate for the large subpopulations analyzed by EPA, the limitations of USDA's food consumption survey discussed above raise questions about its usefulness for even the large subpopulations.

EPA did not calculate and report the precision level (sampling error) of exposure estimates based on data from the 1977-78 survey although the need for this information was identified in 1986, when EPA first began using these data. Without this information, EPA officials cannot be sure whether the specific residue limits they establish partly on the basis of exposure estimates adequately protect all subpopulations from potentially unsafe pesticides. EPA believes that while calculating the precision of estimated exposures for subpopulations will be appropriate in some instances, it may not be worthwhile to do so routinely.

EPA did not participate in the 1987-88 survey's sampling design. While USDA had informed EPA of the expected sample size in 1985—2 years prior to the survey's implementation—and requested input concerning the survey's design, EPA did not comment to USDA because it believed the smaller sample size would not be a major problem.

Background

EPA registers pesticides and establishes maximum allowable pesticide residues (called tolerances) in or on food by authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Food, Drug, and Cosmetic Act (FFDCA). FIFRA authorizes EPA to register pesticides for specific uses and to take regulatory action—such as denying, canceling, or restricting a pesticide's use—if the pesticide presents a significant health or environmental risk. Under FFDCA, EPA assesses the amount of pesticide residue that can be safely left in or on food.[1]

In 1986 EPA began estimating dietary exposure to pesticide residues for tolerance assessments using a computerized system and data collected by USDA's 1977-78 Nationwide Food Consumption Survey. In addition to individual food intake information obtained from over 30,000 people, the survey provides such data as an individual's age, gender, weight, race, and place of residence. These data, combined with residue data

[1] Appendix I describes the tolerance assessment process in detail.

(usually tolerance levels), allow EPA to estimate exposure for 22 distinct subpopulations who, because of their diets, may be exposed to unsafe pesticide levels. Prior to 1986 EPA calculated exposure using USDA's 1965 survey data and a "food factor" method that provided only an average exposure estimate for the total U.S. population.

EPA is updating the food consumption data with USDA's 1987-88 survey results to reflect the current eating habits of Americans. The next major update is scheduled to occur after the 1997-98 survey has been conducted. (See app. I for more complete information on USDA's Nationwide Food Consumption Surveys.)

USDA Survey Data of Little Value for Reliable Subpopulation Estimates

Because they are based on a sample of the population, EPA's pesticide exposure estimates are subject to sampling error. A sampling error (usually expressed as a plus or minus figure) indicates how closely one can reproduce from a population estimate the results that would be obtained by taking a complete population count. Adding the sampling error to and subtracting it from the estimate produces upper and lower bounds for each estimate. This range is called a confidence interval. The magnitude of the error will depend in part on the number of individuals sampled (sample size). Generally, the larger the sample is, the smaller the error will be. Table 1 summarizes, by subpopulation category, both the number of individuals included in the USDA surveys and our estimates of the potential magnitude of sampling error associated with the number of individuals in each subpopulation.

Table 1: Potential Magnitude of Sampling Error for Average Exposure Estimates, by Subpopulation Category

	1977-78 Survey		1987-88 Survey	
Subpopulation	**Number**	**Error[a] (in percentage)**	**Number**	**Error[a] (in percentage)**
Spring season	8,778	12.6	1,860	27.3
Summer season	6,585	14.5	2,229	24.9
Fall season	7,695	13.4	3,507	19.9
Winter season	7,713	13.4	2,576	23.2
Northeast region	7,211	13.8	2,075	25.8
North Central region	7,859	13.3	2,654	22.8
Southern region	10,751	11.3	3,521	19.8
Western region	4,949	16.7	1,922	26.8
Hispanics	1,733	28.2	444	55.8
Non-Hispanic whites	24,581	7.5	8,296	12.9
Non-Hispanic blacks	4,047	18.5	1,149	34.7
Non-Hispanic others	330	64.7	283	69.9
Nursing infants < 1 year	109	112.6	45	175.3
Non-nursing infants < 1 year	457	55.0	121	106.9
Females 13+ years, pregnant	214	80.4	99	118.2
Females 13+ years, nursing	87	126.1	55	158.6
Children 1-6 years	3,663	19.4	1,006	37.1
Children 7-12 years	4,309	17.9	918	38.8
Males 13-19 years	2,541	23.3	454	55.2
Females 13-19 years	2,629	22.9	503	52.4
Males 20 years and older	7,027	14.0	3,158	20.9
Females 20 years and older	10,035	11.7	3,967	18.7
U.S. total	30,770	6.7	10,172	11.7

[a]Degree to which hypothetical exposure estimate can vary at the 95-percent confidence level, expressed as sampling error divided by exposure estimate of 0.1.

Note: In calculating the sampling error in table 1, we made two assumptions. Since we did not have the information that had been collected on each individual surveyed, we could not calculate the sampling error for average exposure levels for each subgroup. Therefore, we assumed EPA's risk analysis estimated that 10 percent of the sample was exposed to pesticide levels above the acceptable level (reference dose), allowing us to calculate the sampling error for this estimate. We also assumed that the sampling error we calculated would be typical for errors for average exposure levels. In addition, because the exposure estimates are based on a complex area probability sample, the magnitude of error is likely to be larger than it would be in a simple random sample. Therefore, the sampling error we computed for each subgroup reflects the error associated with the survey's sample size multiplied by a factor of two to account for the increase in sampling error associated with the survey's sampling design.

The potential error for all exposure estimates increased from 1977-78 to 1987-88, as shown in table 1. For estimates for the total U.S. population and subpopulations with thousands of individuals, this increase is not likely to matter. However, our analysis indicates that EPA's ability to adequately base tolerance assessments on exposure estimates for the five smallest subpopulations—namely nursing and nonnursing infants, nursing females, pregnant females, and non-Hispanic others (such as Asians and Native Americans)—may be compromised because the sampling error for these subpopulations based on the 1987-88 data can range from nearly 70 percent to up to 175 percent of the estimate. Some federal agencies responsible for the administration of major national surveys, such as the National Center for Health Statistics, consider estimates too unreliable to report when the sampling error is 60 percent or more.

Additionally, EPA's ability to adequately base assessments on exposure estimates for three other subpopulations with fewer than 500 or so individuals may also be affected. As shown in table 1, the sampling error for these groups—Hispanics, males 13 to 19 years old, and females 13 to 19 years old—is more than 50 percent of the estimate. USDA, in draft documentation describing its 1987-88 survey results, states that estimates with sampling errors in excess of 50 percent should be used with caution.

EPA considers denying a pesticide's registration if average exposures exceed EPA's acceptable level (reference dose). In the hypothetical example presented in appendix I (table I.1), only two subpopulations—nonnursing infants and children 1 to 6 years old—would have average exposures that exceed EPA's acceptable level. However, the sampling errors we computed for these exposure estimates in table 1 could cause them to vary by 106.9 percent and 37.1 percent, respectively. These sampling errors would result in exposure estimates that range from 0 to 349.0 percent of the acceptable level for nonnursing infants and from 65.4 to 142.5 percent for children 1 to 6 years old, as shown in appendix II.[2] This demonstrates that knowing the sampling error is important because only by incorporating the sampling error can EPA determine with confidence whether estimated exposures for some subpopulations are above or below 100 percent of the acceptable level and thus whether these estimates are reliable in determining that a proposed tolerance level is within acceptable limits.

[2]Appendix II illustrates the effect of sampling error on average estimated exposures to a hypothetical chemical for the total U.S. population and 22 subpopulations.

EPA has contracted for studies to determine the feasibility of using additional, alternative food consumption data to either replace or supplement the survey data for particular subgroups, such as infants. EPA is also exploring ways of incorporating into the data base additional data for the entire population. EPA expects the results of these feasibility studies to be available in June 1991.

EPA Has Not Determined Precision Levels for Exposure Estimates

EPA did not address the need for calculating and reporting sampling errors identified in 1986, when it began using the 1977-78 data. Consequently, EPA does not now know the precision level of exposure estimates based on these data.

In 1985, uncertain of the 1977-78 survey's adequacy for use in estimating exposure for 22 subpopulations, EPA contracted for an independent assessment of the survey data. The statistical contractor's assessment uncovered a number of limitations in the survey, and these were reported to EPA in 1986.

One of these limitations concerned the survey's sample size for certain subgroups. According to the contractor's report, for most subgroups the sample sizes provided by the 1977-78 survey were adequate for estimating possible dietary exposure to pesticide residues, but for some subpopulations "the sample sizes were too small to be statistically credible." These groups were nursing infants, nursing women, and other non-Hispanic minority groups. The report recommended, among other actions, that EPA calculate the precision of its food consumption and population exposure estimates used in making tolerance decisions. Providing an estimate's precision level is consistent with the reporting practices of a number of federal statistical agencies.

EPA decided not to calculate and report any precision levels at all. According to the contractor, EPA was concerned that reporting precision levels in the food consumption estimates would underestimate the level of precision in estimates of population exposure. Because EPA uses two data bases—food consumption and residue level—its position was that since only the food consumption error was quantifiable, it did not want to report any measure of error that was known to be an underestimate and that could therefore be misinterpreted. The statistical contractor disagreed with EPA's position and concluded that analyzing the precision of food consumption estimates would help assess the adequacy of findings generated by the data.

Thus, EPA has been basing its tolerance decisions, in part, on exposure estimates that may lack the precision necessary for setting tolerances. In table 1 our analysis of sampling error shows that for four subpopulations (non-Hispanic others, nursing infants, pregnant females, and nursing females) the potential exists for significant error in exposure estimates calculated with the 1977-78 data. According to the Dietary Exposure Section Head, EPA has no plans to calculate and report the precision of estimates derived from the 1977-78 data primarily because changing the computer programs and data bases for the remaining time that the 1977-78 data will be used does not appear worthwhile.[3]

EPA's contract for incorporating the 1987-88 data into its automated dietary risk evaluation system calls for the system to be capable of providing precision levels of exposures based on the new data. EPA anticipates that, as a result of adding this capability, data processing will require considerably more computer time. Consequently, it has made no firm decision to calculate precision levels in all instances. EPA is currently considering criteria for determining when such calculations would be appropriate. For example, according to one official, it may be appropriate to calculate precision levels only when estimated exposures are 80 percent or more of the acceptable level.

EPA Did Not Participate in Design of USDA Survey

In 1985, in order to make the 1987-88 Nationwide Food Consumption Survey data useful for programs besides nutrition programs, USDA sent inquiries asking for input on survey design to EPA and about 90 other data users in the federal government, industry, and academia. Drafts of the survey questionnaires, as well as the proposed survey design and sample, were included for comment and suggestions. EPA, however, did not comment on the expected sample size.

EPA's tolerance assessment staff supervisor at the time told us that he discussed his initial concerns about the reduced sample size with EPA's management information system contractor responsible for developing the automated risk evaluation system. The contractor's statisticians indicated that the smaller sample size would be a problem for some of

[3]EPA received an advance release of the 1987-88 survey data in July 1990 and confirmation of the survey's low response rate in September 1990. Uncertain of the effect of nonresponse on the data's quality, EPA was waiting for the findings and conclusions of USDA's independent expert panel on total data integrity before proceeding to use the data in assessing tolerances. The panel was convened by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology under contract with USDA in February 1991. In May 1991 the panel concluded that the survey data should not be used unless the greatest caution is employed. EPA expects to make a final determination on whether to use the data in late May 1991.

the smaller subpopulations, such as infants, but would be adequate for the overall population and larger subpopulations. On the basis of this information, this official decided the issue was not worth pursuing and did not communicate any concern about the sample size to USDA.

According to USDA officials, increasing the survey's sample size alone would not have improved coverage of subpopulations such as nursing and nonnursing infants to the degree needed by EPA. One alternative for obtaining statistically adequate numbers would be to design the survey with sufficient oversampling of these subpopulations.

Conclusions

Neither the 1977-78 nor the 1987-88 Nationwide Food Consumption Survey sampled subpopulations such as infants and pregnant females in numbers large enough to permit precise estimates of their dietary exposure to pesticide residues. Additionally, two EPA contractors have raised concerns about the small sample sizes for certain subpopulations. Because of the potential magnitude of error in exposures estimated for these subpopulations, the estimates may be of little practical value in determining whether a pesticide tolerance is above or below levels likely to cause adverse health effects. These groups could be exposed to higher residue levels than considered safe unless EPA, when using the 1987-88 survey data, gives them careful attention in making inferences about their exposure levels or provides information on the precision level of estimated exposures.

EPA does not know the precision level of exposure estimates based on the 1977-78 survey data and has not decided whether to provide this information routinely for the 1987-88 survey data's use. Calculating and reporting precision levels can help to prevent inappropriate interpretations of or unrealistic expectations for exposure estimates used in setting pesticide tolerances and thus help ensure that tolerances provide adequate protection from unsafe residue levels for all subpopulations.

Because information on food consumption patterns serves as a basis for predicting the safety level of pesticide residues, EPA needs to increase its effort to understand its data needs in this area and communicate them to appropriate USDA officials. For example, it is clear that EPA needs to improve coverage of subpopulations such as infants and pregnant women because their occurrence in USDA's nationwide samples is not large enough to permit an accurate assessment of their dietary patterns. Perhaps USDA could design the survey to include these groups in statistically sufficient numbers, or perhaps, if it is more cost-effective and appropriate, EPA could arrange for special surveys capable of making estimates for these groups.

Recommendations

In order to identify and protect all subpopulations at risk from pesticide residues, we recommend that the Administrator, EPA, require the agency to calculate the precision level of exposure estimates where appropriate and use this information to determine the validity of both new and existing tolerances.

In addition, we recommend that the Administrator, EPA, establish a work group to define its food consumption data needs and consult with USDA to determine the best means of obtaining adequate data to meet these needs.

To determine the way in which exposure estimates are calculated and used in setting tolerances, we reviewed relevant dietary risk evaluation system documentation and met with officials from EPA's Office of Pesticide Programs in both the Health Effects and Registration Divisions. To obtain information on both the 1977-78 and 1987-88 Nationwide Food Consumption Surveys, we met with USDA officials in the Human Nutrition Information Service and reviewed relevant USDA documents on the 1987-88 survey's design and methodology. We discussed the factual information contained in this report with responsible officials at EPA and USDA. These officials agreed with the facts presented, and their views have been incorporated into the report where appropriate. As requested, however, we did not obtain official agency comments on the report.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time we will send copies to the appropriate congressional committees; the Administrator, EPA; and other interested parties. We will make copies available to others upon request.

This report was prepared under the direction of Richard L. Hembra, Director, Environmental Protection Issues, who may be reached on (202) 275-6111. Major contributors are listed in appendix III.

Sincerely yours,

J. Dexter Peach
Assistant Comptroller General

Contents

Abbreviations

EPA	Environmental Protection Agency
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAO	General Accounting Office
HNIS	Human Nutrition Information Service
RCED	Resources, Community, and Economic Development Division
USDA	U.S. Department of Agriculture

Background and Methodology

The Environmental Protection Agency (EPA) was made responsible for registering pesticides and establishing tolerances by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Food, Drug, and Cosmetic Act (FFDCA). FIFRA authorizes EPA to register pesticide products for specific uses and to deny a new registration or restrict, cancel, or suspend an existing registration if the agency finds that a pesticide product presents an unreasonable risk to human health or the environment. FIFRA amendments of 1972, 1978, and 1988 require EPA to reregister all previously registered pesticides, giving priority to pesticides used on food. Under FFDCA, EPA is required to establish maximum allowable levels of pesticide residues (called tolerances) if a pesticide remains in or on food or animal feed and to consider whether the tolerance protects human health while also considering factors such as the production of an adequate, wholesome, and economical food supply. Under EPA regulations, tolerances are a prerequisite to registering a pesticide for a food use.

Overview of Tolerance Setting

Tolerances are established after EPA's review of a petition from a pesticide registrant. The petition proposes a residue level that the registrant believes to be safe and suitable to cover residues resulting from the proposed pesticide use. This proposed level is derived from required residue studies and health effect studies, including acute (short-term) dosing and chronic (long-term) feeding, reproductive effects, cancer, genetic change, and birth defect tests. EPA examines and evaluates the petitioner's data to determine an acceptable daily intake level (which EPA scientists now call a reference dose) that would not cause an appreciable health risk to humans and an appropriate tolerance level.

By combining the proposed tolerance level with food consumption estimates, EPA calculates maximum potential dietary exposure estimates for the total U.S. population and 22 subpopulations with unique food consumption patterns. EPA compares the exposure estimates to a pesticide's acceptable daily intake level to determine if the tolerance level is within acceptable limits. If the exposure estimates exceed an acceptable level, EPA revises the estimates using residue levels consumers are more likely to experience. (Consumers may experience less than maximum allowable levels because residues can decrease due to food storage time and other factors.) If the revised estimates exceed an acceptable level, EPA generally advises the registrant that the proposed tolerance cannot be approved.

To illustrate, table I.1 shows estimated maximum average exposures to a hypothetical pesticide for the total U.S. population and 22 subpopulations.

Table I.1: Summary of Estimated Average Exposures to Hypothetical Chemical for Total U.S. Population and 22 Subpopulations

	Estimated average exposures at proposed tolerance level	
Subpopulation	**Exposure (in mg/kg/day)[a]**	**Exposure (as percentage of RfD)[b]**
Spring season	.004687	37.5
Summer season	.004830	38.6
Fall season	.005094	40.8
Winter season	.005051	40.4
Northeast region	.005036	40.3
North Central region	.005079	40.6
Southern region	.004453	35.6
Western region	.005315	42.5
Hispanics	.005963	47.7
Non-Hispanic whites	.004902	39.2
Non-Hispanic blacks	.004463	35.7
Non-Hispanic others	.005290	42.3
Nursing infants (<1 year)	.004974	39.8
Nonnursing infants (<1 year)	.021088	168.7
Females (13+ years, pregnant)	.003444	27.6
Females (13+ years, nursing)	.004354	34.8
Children (1 to 6 years old)	.012993	103.9
Children (7 to 12 years old)	.008330	66.6
Males (13 to 19 years old)	.005426	43.4
Females (13 to 19 years old)	.004166	33.3
Males (20 years and older)	.003164	25.3
Females (20 years and older)	.002720	21.8
Total U.S. population	.004915	39.3

[a]EPA expresses exposure as milligrams of a pesticide residue per kilogram of body weight per day.

[b]Reference Dose (.0125 mg/kg/day).
Source: EPA.

In this example, exposure at the proposed tolerance level was compared with a specific acceptable daily intake level. The results are expressed as the percentage of the acceptable daily intake level (reference dose) that the exposure estimate occupies. The average exposure for the U.S.

population was calculated to be 39.3 percent of the acceptable level. In this hypothetical example, two subpopulations—namely, nonnursing infants and children 1 to 6 years of age—would have average exposures that are substantially higher than the U.S. population average and that exceed EPA's acceptable level of 100 percent. Therefore, further consideration would occur to determine exposure at actual residue levels.

EPA's Dietary Risk Evaluation System

In establishing pesticide tolerances, EPA uses a computer-based system known as the dietary risk evaluation system or DRES. The system permits EPA to calculate exposure estimates for both daily and average lifetime food consumption patterns and thus determine risk from either a day's or lifetime's exposure. EPA began using the computerized system in 1986 for reviewing pesticides of special concern, establishing tolerances for the first food use of new pesticides, and reassessing existing tolerances for the reregistration program. In April 1988 EPA extended the system's use to include establishing tolerances for new food uses of existing pesticides.

USDA's Nationwide Food Consumption Surveys

To develop dietary exposure estimates for assessing tolerances, EPA uses data collected by the U.S. Department of Agriculture's (USDA) Nationwide Food Consumption Survey. This survey is conducted every 10 years as part of the National Nutrition Monitoring System to determine the nutritional status of Americans by age, gender, and other characteristics. The most recent survey was completed in 1988; the next survey is scheduled to be conducted in 1997-98.

Data from the surveys are used by a number of federal agencies concerned with the nutritional, economical, and safety aspects of food consumption; by nutrition and health researchers; by industry; and by the Congress. For example, the data support various analyses by USDA agencies responsible for federal food assistance programs, an area that received about $23 billion in fiscal year 1991 appropriations.

Several sources have criticized the USDA surveys. In reports issued in 1977-78, we cited weaknesses such as low income family samples that were too small for evaluating food assistance programs and delayed release of the data to users.[1] In a 1989 congressional hearing on nutrition monitoring, the 1977-78 survey was faulted for being outdated by

[1] Nationwide Food Consumption Survey: Need for Improvement and Expansion (CED-77-56, Mar. 1977) and Future of the National Nutrition Intelligence System (CED-79-5, Nov. 1978).

the time the data were reported and for lack of sufficiently large samples of subpopulations, such as infants and preschool children, who are considered to be at high risk nutritionally.

Because of budgetary constraints, the 1987-88 survey was intended to sample fewer individuals than the 1977-78 survey. In addition, a low response rate affected the ultimate number of individuals surveyed. Accordingly, food consumption data were collected from 10,172 individuals in 1987-88, as compared with 30,770 individuals in 1977-78. The 1987-88 data were released to the public in October 1990.

Objectives, Scope, and Methodology

Concerned by the reduced sample size, the Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, asked us to review the adequacy of USDA's 1987-88 Nationwide Food Consumption Survey data used by EPA for estimating dietary exposure to pesticide residues in establishing tolerances. The objectives of our review were to determine

- the adequacy of USDA's 1987-88 survey for EPA's future exposure estimates;
- the adequacy of EPA's current exposure estimates, based on the 1977-78 survey; and
- EPA's involvement in designing the 1987-88 survey.

To determine the way in which exposure estimates are calculated and used in setting tolerances, we reviewed relevant documentation on EPA's dietary risk evaluation system and met with EPA Office of Pesticide Programs officials in both the Health Effects and Registration Divisions. We focused our review on the effects of the reduced sample size on EPA's routine analysis of chronic (long-term) health risks since this analysis is performed for almost all tolerance requests. (EPA also performs analyses for cancer and acute [short-term] risks, using different procedures.) We also reviewed dietary risk evaluation files and interviewed former program staff for information pertaining to EPA's involvement in the 1987-88 survey design.

To obtain information on both the 1977-78 and 1987-88 Nationwide Food Consumption Surveys, we met with USDA officials in the Human Nutrition Information Service (HNIS) and reviewed relevant USDA documents on the survey's design and methodology. To evaluate the impact of the 1987-88 survey's reduced sample size, we obtained documentation from HNIS officials on the number of individuals surveyed in each EPA subpopulation category. Using this information we estimated the potential magnitude of error introduced because of sample size in order to identify those subpopulations' exposure estimates that would most likely be affected by the reduced sample size. It is possible that estimated exposures for subpopulations other than those we identified could also be affected.

Our work was performed between April 1990 and December 1990 in accordance with generally accepted government auditing standards. During the course of our work, we sought the views of responsible officials at EPA and USDA and incorporated their views where appropriate. However, as requested, we did not obtain official agency comments on this report.

Effect of Sampling Error on Average Estimated Exposures to Hypothetical Chemical for Total U.S. Population and 22 Subpopulations

Subpopulation	Sampling error (in percentage)[a]	Exposure estimate (as percentage of RfD)[b]	Lower bound and upper bound of exposure estimate[c] (as percentage of RfD)[b]
Spring season	27.3	37.5	27.3 to 47.7
Summer season	24.9	38.6	29.0 to 48.3
Fall season	19.9	40.8	32.6 to 48.9
Winter season	23.2	40.4	31.0 to 49.8
Northeast region	25.8	40.3	29.9 to 50.7
North Central region	22.8	40.6	31.4 to 49.9
Southern region	19.8	35.6	28.6 to 42.7
Western region	26.8	42.5	31.1 to 53.9
Hispanics	55.8	47.7	21.1 to 74.3
Non-Hispanic whites	12.9	39.2	34.2 to 44.3
Non-Hispanic blacks	34.7	35.7	23.3 to 48.1
Non-Hispanic others	69.9	42.3	12.7 to 71.9
Nursing infants (<1 year)	175.3	39.8	0.0 to 109.5
Nonnursing infants (<1 year)	106.9	168.7	0.0 to 349.0
Females (13+ years, pregnant)	118.2	27.6	0.0 to 60.1
Females (13+ years, nursing)	158.6	34.8	0.0 to 90.1
Children (1 to 6 years old)	37.1	103.9	65.4 to 142.5
Children (7 to 12 years old)	38.8	66.6	40.8 to 92.5
Males (13 to 19 years old)	55.2	43.4	19.4 to 67.4
Females (13 to 19 years old)	52.4	33.3	15.9 to 50.8
Males (20 years and older)	20.9	25.3	20.0 to 30.6
Females (20 years and older)	18.7	21.8	17.7 to 25.8
Total U.S. population	11.7	39.3	34.7 to 43.9

[a]Sampling error for average estimated exposures based on the 1987-88 data from table 1.

[b]Reference Dose (.0125 mg/kg/day).

[c]Lower bound is the exposure estimate minus the sampling error; upper bound is the exposure estimate plus the sampling error.

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