

**SUPPORTING STATEMENT FOR
AN INFORMATION COLLECTION REQUEST (ICR)**

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection: **Data Acquisition for Anticipated Residue and Percent of Crop Treated**
OMB NO.: 2070-0164; **EPA NO.:** 1911.02

1(b) Short Characterization/Abstract

This information collection request (ICR) involves an information collection activity related to the statutorily mandated re-evaluation of previous Agency decisions regarding the establishment of a tolerance (maximum residue limit) for pesticide residues on food or feed crops.

The use of pesticides to increase crop production often results in pesticide residues in or on the crop. To protect the public health from unsafe pesticide residues, the Environmental Protection Agency (EPA) sets limits on the nature and level of residues permitted pursuant to section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA). A pesticide may not be used on food or feed crops unless the Agency has established a tolerance for the pesticide residues on that crop, or established an exemption from the requirement to have a tolerance.

It is EPA's responsibility to ensure that the maximum residue levels likely to be found in or on food/feed are safe for human consumption through a careful review and evaluation of residue chemistry and toxicology data. In addition it must ensure that adequate enforcement of the tolerance can be achieved through the testing of submitted analytical methods. Once the data are deemed adequate to support the findings, EPA will establish the tolerance or grant an exemption from the requirement of a tolerance.

This ICR will enable EPA's Office of Pesticide Programs (OPP) to obtain information needed to re-evaluate the Agency's original tolerance decisions as mandated by the Food Quality Protection Act of 1996 (FQPA), which amended the two primary statutes regulating pesticides, i.e., FFDCA and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Among other things, FQPA amended FFDCA to authorize the Agency to use anticipated or actual residue (ARs) data and percent crop treated (PCT) data to establish, modify, maintain, or revoke a tolerance for a pesticide residue. However, the law also requires that tolerance decisions based on ARs or PCT data be verified to ensure that residues in or on food are not above the residue levels relied on for establishing the tolerance.

In order to conduct the required re-evaluation, a Pesticide Registrant may be required to submit specific data necessary to demonstrate that residues do not exceed the residue levels used to establish the tolerance.

The burden and costs associated with establishing a tolerance or an exemption from a tolerance are covered under ICR number 2070-0024, *Tolerance Petitions for Pesticides on Food/Feed Crops and New Inert Ingredients*. This ICR only addresses the burden and costs

associated with the information collection activities related to the re-evaluation of tolerances pursuant to FFDCCA section 408(b)(2).

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

FIFRA sections 3(a) and 12(a)(1) require a person to register a pesticide product with the EPA before that product may be lawfully sold or distributed in the United States. A pesticide registration is a license that allows a pesticide product to be sold and distributed for specific uses under specified terms and conditions such as use instructions and precautions. A pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5). Under FFDCCA section 408, before a pesticide may be used on food or feed crops, the Agency must establish a tolerance for the pesticide residues on that crop or established an exemption from the requirement to have a tolerance.

The authority for the information collection activities contained in this ICR can be found in FFDCCA section 408(b)(2)(E) and (F), which authorizes the Agency to use anticipated or actual residue (ARs) data and percent crop treated (PCT) data to establish, modify, maintain, or revoke a tolerance for a pesticide. The FFDCCA requires that if AR data are used, data must be reviewed five years after a tolerance is initially established. If PCT data are used, the FFDCCA affords EPA the discretion to obtain additional data if any or all of several conditions, including but not limited to the following, are met:

- the existing data have been found unreliable;
- exposure estimates underestimate exposures for any significant population group;
- dietary exposure must be re-evaluated periodically

As noted above, when re-evaluating tolerance actions, Section 408(f) of FFDCCA generally requires EPA to issue DCIs whenever ARs data have been relied on, and affords the EPA the discretion to issue DCIs when PCT data have been relied on. OPP issues a DCI to affected registrants under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(2)(B). The data obtained from the DCIs are needed to reassess the risk and to confirm that use of a pesticide is not likely to cause unreasonable adverse effects to human health or the environment.

2(b) Practical Utility/Users of the Data

OPP will evaluate the data obtained from registrants to ensure that residues in or on food are not above the residue levels relied on for establishing the tolerance. If the submitted residue data demonstrates that the residue levels are above the levels relied on for establishing the tolerance, EPA will take appropriate action to modify or revoke the tolerance.

3. NON-DUPLICATION, CONSULTATIONS AND OTHER COLLECTION CRITERIA

3(a) Non-duplication

OPP supports several activities to eliminate duplication and promote efficiency in information collection efforts for registration. Before any DCI is conducted, internal files are referenced to determine whether the required data is already on hand. No other federal agency regulates these chemicals as comprehensively as EPA does. Since much of the percent-crop-treated information can be obtained internally, DCIs will only be issued when more data is necessary. The data for anticipated residues, on the other hand, is unique to the requirements of FIFRA, and, therefore, must be submitted to the Agency.

OPP also publishes a list of data submitters and encourages the industry to act cooperatively in the development of data or in its use. OPP allows cost-sharing agreements among manufacturers of specific pesticide chemicals in order to minimize the duplication of laboratory tests conducted for this program. All DCI notices explain the statutory provisions for cost-sharing agreements under FIFRA.

3(b) Public Notice Required Prior to ICR Submission to OMB

In preparing to renew this ICR, EPA will publish a notice in the Federal Register which will provide a 60-day public notice and comment period. The Agency will consider any comments on this ICR in response to that notice.

3(c) Consultations

Before a particular DCI is issued under either program, the procedures for both programs provide several opportunities for consultations with the affected registrants, as well as with the public and other interested parties.

In the initial stage of AR/PCT reviews, the Agency announces its intent to conduct such a review and require additional studies. Registrants and other interested parties have the opportunity to comment on the Agency's intent. Generally the Agency consults with registrants before a data call-in notice is issued to discuss the Agency's need for particular information and the protocol to be used to conduct the study. OPP is always open to communications with registrants concerning any issue they may have with the requirements for data. As mentioned, registrants may request waivers of data requirements if they believe that OPP can properly evaluate their pesticide without additional data. The Agency may modify its DCI requirements if warranted by information provided by registrants or the public. In addition, registrants may respond to the DCI by requesting waivers of data requirements if they believe that OPP can properly evaluate their pesticide without additional data. The Agency has already on several occasions discussed the statutory requirements and data requirements for the AR/PCT reviews with the stakeholders.

In addition, during preparation of this ICR renewal, EPA staff will contact representatives from a cross-section of respondents by e-mail and telephone to seek feedback on the burden estimates in the ICR, the clarity of instructions provided, the feasibility of reporting the data by electronic means, and other questions pertaining to the requirements of the program.

3(d) Effects of Less Frequent Collection

Information is collected one time within the five years preceding the reliance on ARs or PCT data. This one time collection is required by (FFDCA 408(b)(2)(E)(I) and 408(b)(2)(F) and cannot be collected less frequently.

3(e) General Guidelines

The only guideline established under the Paperwork Reduction Act (PRA) that is exceeded in this collection is the time period for retaining records. EPA requirements in 40 CFR 169.2(k) state that records containing research data relating to registered pesticides be retained as long as the registration is valid and the producer remains in business. Registrations are valid until they are canceled by the Agency, either by request of the registrant or on the initiative of EPA. Since most pesticides remain on the market for 15 to 30 years, the PRA guidelines specifying that data other than health, medical or tax records not be required to be retained for more than three years is exceeded in this program.

3(f) Confidentiality

Except as provided in FIFRA section 10(d)(1)(A), (B) or (C), health and safety data submitted by registrants under FIFRA must be made available by the Agency upon request from anyone not affiliated with a multi-national pesticide firm. These exceptions, however, specifically prohibit disclosure of the inert ingredients in a pesticide, or of its manufacturing or quality control processes.

Registrants may claim at the time of submission that specific data are subject to treatment as confidential for reasons other than falling within the exclusions for mandatory release. All data subject to such claims, or falling within FIFRA section 10(d)(1)(A), (B), or (C) are handled strictly in accordance with the provisions of the FIFRA Confidential Business Information Security Manual. The manual requires that all CBI must be marked or flagged as such, all CBI must be kept in secure (double-locked) areas, and all CBI intended to be destroyed must be cleared by a Document Control Officer and shredded.

3(g) Sensitive Questions

No information of a sensitive or private nature is requested in conjunction with this information collection activity, and this information collection activity complies with the provisions of the Privacy Act of 1974 and OMB Circular A-108.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents/NAICS Codes

The North American Industrial Classification System (NAICS) code for respondents to this ICR is **325320** (Pesticide and other Agricultural Chemical Manufacturing).

4(b) Information Requested

(i). Data items, including record keeping requirements

The kinds of data that may be the subject of a DCI under this ICR may include one or more of the following data items, which are included in 40 CFR Part 158, Data Requirements for Pesticide Registration:

- 1) Monitoring data (PDP, FDA, FSIS, States, special monitoring [market basket, single serving, etc.]
- 2) Field trials,
- 3) Processing studies,
- 4) Reduction in residue data (washing, peeling, cooking, etc.),
- 5) Livestock feeding studies
- 6) Metabolism studies
- 7) Percent crop treated data

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SOURCE OF DATA USED IN ANTICIPATED RESIDUES	DATA NEEDED TO CONFIRM ANTICIPATED RESIDUES 5 YEARS LATER
Monitoring data (Pesticide Data Program (PDP), FDA, FSIS, States, special monitoring [market basket, single serving, etc.])	Updated monitoring data are required. The registrant may use any of the publicly available sources used by the Agency. Data should reflect the time period since establishment of the tolerance. If data are not available from the above sources, then the registrant must conduct an appropriately designed monitoring study. The design of this study must be approved by the Agency.
Field trials	The registrant must <u>EITHER</u> verify that the pesticide formulations, application rates, timing, intervals, geographic distribution of use, etc., have not changed <u>OR</u> provide field trial data that reflect any changes in the use pattern that may lead to increased residues.
Processing studies Reduction in residue data (washing, peeling, cooking, etc.)	The registrant must <u>EITHER</u> certify that commercial processing practices have not changed significantly <u>OR</u> provide new processing studies reflecting current commercial practices. A similar requirement applies to any study used to demonstrate reduction in residues between farm gate and consumption.
Livestock feeding studies and metabolism studies	Registrant must <u>EITHER</u> verify that the dietary burden calculations that were incorporated in the original AR derivation for meat, milk, poultry or eggs are still valid <u>OR</u> provide a new animal feeding study that reflects current feeding practices. Dietary burden calculations could change due to increased residue levels on feed items or from changes in the relative abundance or use of a particular feed item over time.

EPA has published guidelines for studies listed in 40 CFR Part 158, Data Requirements. Internal guidelines have also been established for monitoring studies which require a registrant to submit and obtain approval of the study protocol prior to initiating a study. The protocol must describe crops and pesticides to be covered by the study. After approval, the applicant must adhere to the protocol or seek approval for major deviations. SOP No. HED AR-1 contains the specific requirements when ARs are used (see Attachment A).

If EPA relies on ARs data when establishing or reassessing a tolerance, it generally must issue a DCI, and if the EPA used the percent of crop treated data estimates for a tolerance action, it may generally issue a DCI. A DCI is a letter sent to the registrant that explains the data submission requirement, requests specific data, sets out a time frame for a response to EPA, and provides applicable forms and guidelines to assist the registrant with the completion of the DCI request. A registrant must respond within 90 days of receipt of the DCI. The response must describe plans to submit the required data in accordance with the time frame specified, and, if applicable, contain suggested protocols for monitoring studies. Failure to generate the requested data, or respond to the DCI in a timely manner, could result in Agency action to modify or revoke the tolerance.

There are two main categories of applications for this collection: those requiring submission of a full complement of supporting data, (e.g., new chemicals, and biorationals); and those requiring submission of little or no data, (e.g., "me-too" products) for previously registered chemicals and use patterns. Applicants for a "me-too" product (i.e., a pesticide claimed to be substantially similar in composition and use to a product previously registered by the EPA) may be required only to use EPA Form 8570-34, Certification with Respect to Citation of Data (in Pesticide Registration (PR) Notice 98-5), and EPA Form 8570-35, Data Matrix (also in PR Notice 98-5), to certify that the applicant intends to rely on data previously submitted to the EPA by another producer, the applicant has contacted the appropriate company (owning the data that the applicant is referencing), and the applicant has offered to pay reasonable compensation for the use of the data. These forms are already approved under ICR number 2070-0060, *Application for New or Amended Registration*.

(ii). Respondent Activities

A registrant must take the following actions to comply with a DCI:

Read instructions	Read the DCI letter to understand what data are to be submitted;
Plan activities	Plan the activities necessary to comply with the DCI. These may include: a) request a waiver; b) agree to do data; c) certify offer of compensation with original data submitter; d) volunteer to cancel the registration of concern; e) claim a generic data exemption;
Create information	Conduct research, administer tests, analyze data to develop studies, perform and report laboratory analyses;
Gather information	Search for existing data that will satisfy the DCI;
Compile and review	Assemble and evaluate data for accuracy and appropriateness for compliance with the DCI;
Complete paperwork	Prepare necessary correspondence documents and packages for submitting data to EPA; and
Submit and file	Transmit the data and other information to EPA and catalog in company files.

5. THE INFORMATION COLLECTED: AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

5(a) Agency Activities

The Agency must perform the following actions to conduct a DCI:

Develop DCI notice	Determine data requirements and prepare the DCI letter identifying all data needed and respondent's options; issue DCI;
Answer questions	Respond to any questions the registrant may have regarding the DCI;
Examine responses and data submissions; archive documents	Examine responses and data submissions for acceptability and responsiveness to DCI; if necessary, clarify or seek additional information from registrant; process, catalog and archive DCI data into the Pesticide Document Management System (PDMS); refer non-responders to the Office of Enforcement and Compliance and Assurance for action;
Analyze data	Conduct scientific reviews of the data; and
Record and store DCI data	Record facts of the submission for compliance monitoring and archive in EPA files.

5(b) Collection Methodology and Management

OPP tracks DCIs and all registrant responses through the Office of Pesticide Programs Information Network (OPPIN), OPP's general purpose action tracking system. Additionally, the Reference Files System (REFS) is used if the registrant voluntarily cancels a product in response to a DCI. The Pesticide Data Management System lists the bibliography of data submitters for the DCI and OPPIN tracks the submissions. All correspondence associated with the issuance and response to the DCI is filed in the master registration file or 'registration jacket' of affected products. Data submitted in response to a DCI is processed, catalogued and archived in the PDMS. Failures to comply with DCI requirements are referred to EPA's Office of Enforcement and Compliance Assurance for appropriate follow-up actions. Records submitted pursuant to a DCI are subject to Freedom of Information Act (FOIA) requests.

5(c) Small Entity Flexibility

Currently, pesticide registrants may be divided into two groups. Approximately 10 percent of the total: manufacture or import chemical active ingredients intended for use as pesticides, sell these active ingredients to other firms for formulation into pesticide products, and/or make the end-products themselves. The second, and by far the larger, group of registrants purchase the active ingredients in their pesticide products from members of the first group, and combine them with pesticide inert ingredients or sometimes simply repackage them to make their end-use products.

This second group is primarily comprised of small businesses. When small businesses use a registered source of the active ingredient to formulate their products, they generally are exempt from

generating health and safety data for pesticide active ingredients ("generic data"). Consequently, they usually need only respond to a DCI for active ingredient data by claiming the "generic data exemption." They do not incur any other information burden associated with the generic data call-in.

5(d) Collection Schedule

DCIs will generally be issued whenever ARs data is relied upon, either to establish new tolerances or reassess existing tolerances. Registrants have five years before data must generally be submitted in support of the ARs used. Data must also be periodically reviewed when PCT estimates are relied upon, but in most cases the Agency will be able to internally collect or generate this data. In cases where the Agency is unable to get the information itself, the registrant must submit data within five years of the use of PCT estimates. A registrant must respond within 90 days of receipt of the DCI. The response must describe plans to submit the required data in accordance with the time frame specified, and, if applicable, contain suggested protocols for monitoring studies. Additional time is provided for development of new studies appropriate to the nature of the studies required.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a) Estimating Respondent Burden

The annual respondent burden for the collection of information associated with this activity is estimated to average between 59 and 13,636 burden hours per DCI, depending upon the type of response requested. The total estimated burden for this ICR of 28,569 burden hours is based on the Agency's estimate of the potential burden and number of responses for each of the following four types of potential DCIs:

- 1) DCI for anticipated residues requiring a base set of data (13,636 hrs.);
- 2) DCI for anticipated residues requiring minimum data (69 hrs.);
- 3) DCI for anticipated residues collected from publically available sources (137 hrs.);
- and
- 4) DCI for percent crop treated using existing information (59 hrs.).

The following information presents the Agency's burden estimates for each type of DCI.

DCI Type 1 - DCI for anticipated residues requiring a base set of data:

Respondent burden hours for generating and submitting data in response to a DCI for anticipated residues requiring a base set of data to be submitted are estimated at 13,636 burden hours per response. EPA also considered the typical burden for reading instructions, planning activities, compiling and reviewing the submission, submitting the data to EPA, and related record keeping in estimating the total per response burden and costs. Using the EPA PDP contracts as the basis, EPA estimated the burden for conducting a monitoring study to gather the necessary data, and the annual respondent cost for meeting 40 CFR part 158 data requirements for anticipated residues. See Table 1.

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Since, in most cases, registrants will be able to get the information from federal and state monitoring programs, EPA estimates that no more than 2 registrants might generate their own monitoring data in response to the DCI. The total burden for this type of DCI is therefore estimated to be 27,272 hours per year for two respondents.

TABLE 1 - Annual Respondent Burden/Cost Estimates for Anticipated Residues Generating Anticipated Residue Data

ACTIVITIES	BURDEN HOURS (per year)			TOTAL	
	Mgmt. \$130	Tech. \$88	Cler. \$40	Hours	Costs
1) Read instructions	2	0	0	2	260
2) Plan activities	4	0	0	4	520
3) Create information	0	13,600	0	13,600	1,196,800
4) Gather information	0	16	0	16	1,408
5) Compile and review	1	8	0	9	854
6) Complete paperwork	2	0	2	4	340
7) Maintain and file	0	0	1	1	40
TOTAL	9	13,624	3	13,636	\$1,200,202

BURDEN: 13,636 hours x Average of 2 responses = 27,272 Total Burden Hours.

DCI Type 2 - DCI for anticipated residues requiring minimum data:

Minimum data captures the burden for cases in which the respondent verifies that nothing has changed; i.e., the formulation, use rate, geographic distribution of use, etc. have not changed since the ARs were used to establish or reassess the tolerance. Average burden hours per respondent for submitting a base set of data for updating use information is estimated at 69 burden hours per year per response. EPA estimates that no more than 20 respondents each year will comply with a DCI by submitting a base set of data for updating use information. As such, the total respondent burden hours per year are estimated at 1,380 hours. See Table 2.

TABLE 2 - Annual Respondent Burden/Cost Estimates for Anticipated Residues Requiring Minimum Data

Collection Activities	Burden Hours (per year)			Total	
	Mgmt. \$130	Tech. \$88	Cler. \$40	Hours	Costs
1) Read Instructions	8	0	0	8	1,040
2) Plan Activities	16	0	0	16	2,080
3) Create Information	0	0	0	0	0
4) Gather Information	0	16	0	16	1,408
5) Compile and Review	2	16	0	18	1,668
6) Complete Paperwork	2	0	8	10	580
7) Submit and File	0	0	1	1	40
Total	28	32	9	69	\$6,816

BURDEN: 69 hours x Average of 10 responses = 690 Total Hours.

DCI Type 3 - DCI for anticipated residues collected from publically available sources:

The average respondent burden for submitting a base set of data for updating monitoring information is estimated at 137 burden hours per year. EPA estimates that an average of 4 respondents each year are likely to be able to comply with a DCI by submitting data from publically available sources. As such, the total annual respondent burden for this type of DCI is estimated to be 548 burden hours. See Table 3.

TABLE 3 - Annual Respondent Burden/Cost Estimates for Anticipated Residues Collected from Publicly Available Sources

Collection Activities	Burden Hours (per year)			Total	
	Mgmt. \$130	Tech. \$88	Cler. \$40	Hours	Costs
1) Read Instructions	8	0	0	8	1,040
2) Plan Activities	16	0	0	16	2,080
3) Create Information	0	0	0	0	0
4) Gather Information	0	60	0	60	5,280
5) Compile and Review	2	40	0	42	3,780
6) Complete Paperwork	2	0	8	10	580
7) Submit and File	0	0	1	1	40
Total	28	100	9	137	12,800

BURDEN: 137 hours x Average of 4 responses = 548 Total Hours.

DCI Type 4 - DCI for percent crop treated using existing information:

The annual per respondent burden for generating percent crop treated estimates using existing information is estimated to be 59 burden hours. Percent crop treated estimates are generally conducted within the Agency, and only in rare instances would a registrant need to gather the information; one per year may be an overestimation. The estimated costs assume that cost of purchasing, or obtaining percent crop treated information derived from existing, contracted data sources. See Table 4.

TABLE 4 - Annual Respondent Burden/Cost Estimates for Percent Crop Treated Using Existing Information

Activities	Burden Hours (per year)			Total	
	Mgmt. \$130	Tech. \$88	Cler. \$40	Hours	Costs
1) Read Instructions	1	1	0	2	218
2) Plan Activities	0	2	0	2	176
3) Create Information	0	8	0	8	704
4) Gather Information	0	22	0	22	1,936
5) Compile and Review	1	20	0	21	1,890
6) Complete Paperwork	1	0	2	3	210
7) Submit and File	0	0	1	1	40
Total	3	53	3	59	\$5,174

BURDEN: 59 hours x average of generating 1 response = 59 Total Hours

6(b) Estimating Respondent Costs

The corresponding estimated respondent cost for this collection is \$2,524,938. Respondent costs are based on managerial, technical and clerical burden hours estimated at \$130, \$88, and \$40 per hour, respectively. EPA has calculated the estimated labor rates for respondents to the requirements of this ICR factoring in an inflation cost index of 1.056 based on the Gross Domestic Product. These labor rates are fully loaded and include benefits and overhead costs.

The total estimated cost for this collection is based on the Agency's estimate of the potential cost and number of responses for each of the following four types of potential DCIs:

- 1) DCI for anticipated residues requiring a base set of data - \$2,400,404
- 2) DCI for anticipated residues requiring minimum data - \$68,160
- 3) DCI for anticipated residues collected from publically available sources - \$51,200;
- and
- 4) DCI for percent crop treated using existing information - \$5,174.

6(c) Estimating Agency Burden and Costs

Annual Agency burden for managing individual information from Type 1, 2 or 3 DCIs is estimated at 99 burden hours per response. The hourly rates are \$96, \$70, and \$33 per hour for management, technical, and clerical staff, respectively. Agency labor rates are based on Office of Personnel Management salary tables for federal employees for the years 1999 through 2001 and include benefits and overhead costs, as well as locality pay for the Washington, DC-Baltimore area. The annual Agency cost for managing an individual response is estimated at \$6,501 per response.

Since the average number of responses each year for these DCIs is estimated to be 16, the total annual burden for the Agency activities is estimated to be 1,584 burden hours, with an associated cost of \$104,016 per year. See Table 5.

TABLE 5 - Annual Agency Burden/Cost Estimates for Processing DCI Types 1-3

Collection Activities	Burden Hours (per year)			Total	
	Mgmt. \$96	Tech. \$70	Cler. \$33	Hours	Costs
Develop DCI notice	1	0	2	3	162
Answer Registrants' questions	0	4	5	9	445
IN-process data submissions	0	0	4	4	132
Analyze data	1	80	0	81	5,696
Record and store DCI data	0	0	2	2	66
Total	2	84	13	99	\$6,501

BURDEN: 99 hours x 16 responses = 1,584 Total Hours

COSTS: \$6,432 x 16 responses = \$104,016 Total Costs

The annual Agency burden for managing individual DCI information for percent crop treated is estimated at 59 hours per response, with an estimated cost of \$3,701 per response. Since the Agency estimates no more than 1 response each year, if any, the total annual Agency burden and cost is 59 burden hours, and \$3,701 See Table 6.

TABLE 6 -Annual Agency Burden/Cost Estimates for Processing DCI Type 4

Collection Activities	Burden Hours (per year)			Total	
	Mgmt. \$96	Tech. \$70	Cler. \$33	Hours	Costs
Develop DCI notice	1	0	2	3	162
Answer Registrants' questions	0	4	5	9	445
IN-process data submissions	0	0	4	4	132
Analyze data	1	40	0	41	2,896
Record and store DCI data	0	0	2	2	66
Total	2	44	13	59	\$3,701

BURDEN: 59 hours x 1 response = 59 Total Hours

COSTS: \$3,701 x 1 responses = \$3,701 Total Costs

6(d) Bottom Line Burden Hours and Cost Table

The total estimated annual respondent burden is 28,569 burden hours (28,509 burden hours for all AR DCI submissions + 59 burden hours for Percent Crop Treated DCI submissions), with an associated cost of \$2,524,938 (\$2,519,764 for all AR DCI submissions + \$5,174 for Percent Crop Treated DCI submissions). See Table 7.

The total estimated annual Agency burden is 1,643 burden hours (1,584 burden hours for all AR DCI submissions + 59 burden hours for Percent Crop Treated DCI submissions)., with an associated cost of \$107,717 (\$104,016 for all AR DCI submissions + \$3,701 for Percent Crop Treated DCI submissions).

	Key Activities	Hours	Costs
Respondents	Total respondent burden/costs for generating anticipated residue data.	27,272	\$2,400,404
	Total respondent burden/costs for submitting minimal anticipated residue data.	690	\$68,160
	Total respondent burden/costs for submitting anticipated residue data from publicly available sources.	548	\$51,200
	Total respondent burden/costs for submitting percent crop treated data using existing information.	59	\$5,174
Total estimated respondent burden/costs.		28,569	\$2,524,938

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Agency	Total Agency burden/costs for managing anticipated residue DCI's	1,584	\$104,016
	Total Agency burden/costs for managing percent crop treated DCI's.	59	\$3,701
Total Agency burden/costs.		1,643	\$107,717

6(e) Reasons for Change in Burden

In the previous ICR, OMB approved 29,807 burden hours, with a cost of \$2,773,866. This ICR renewal request reflects a decrease of approximately 1,238 burden hours for an annual respondent burden of 28,569 hours and a decrease in cost of \$248,928, for an annual respondent cost of \$2,524,938. These reductions are adjustments due to the fact that the Agency expects to issue fewer data call-ins under this program than originally estimated. Oftentimes, data can be acquired more efficiently without issuing a DCI. For example, OPP works closely with USDA's Pesticide Data Program (PDP) which generates publically available monitoring data. OPP can get the PDP monitoring data more quickly and in a format most usable to the Agency by requesting the data directly from USDA. This would eliminate the cost to the pesticide registrants and would save the Agency time and the administrative expense associated with a data-call-in. Similarly, data on changes in processing practices that may lead to increases in residues can more efficiently collected in cooperation with food industry associations. Also, in many cases the Agency can continue to stand by its safety finding without requiring additional data because the risk is so low that even large increases in exposure would not create a risk of concern.

6(f) Burden Statement

The total annual respondent burden for this ICR is estimated to be 28,569 hours, ranging from 59 hours to 13,636 hours per response, depending on the type of DCI.

According to the Paperwork Reduction Act, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection, it is the time reading the regulations, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and completing other required paperwork, and storing, filing, and maintaining the data.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

To comment on EPA's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID No. OPP-2004-0109, which is available for public viewing at the OPP Docket in the Public Information and Records Integrity Branch, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is

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open from 8:30 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

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DRAFT FOR PUBLIC COMMENT

March 31, 2004

ATTACHMENTS TO THE SUPPORTING STATEMENT

ATTACHMENT A: SOP No. HED AR-1. This attachment follows the Supporting Statement in the electronic file.

ATTACHMENT A

SOP No. HED AR-1

Title: Use of Anticipated Residues in Risk Assessment

Revision No. Original

Effective Date: FEB-15-99

1.0 Purpose

To standardize the procedures used by scientists in the Health Effects Division for calculation of anticipated residues.

2.0 Scope

This procedure shall be followed by all HED personnel involved in the manipulation of data to calculate anticipated residues to be used in risk assessment estimates.

3.0 Outline of Procedures

- Regulatory Background
- Interpretations of FFDCA
- Definition of Terms Used in this Document
- Dietary Exposure
- Data Needed to Verify Anticipated Residues
- Non-Detects
- Documentation Requirements

4.0 References

- Federal Food, Drug, and Cosmetic Act (FFDCA)
- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
- Food Quality Protection Act (FQPA)
- Residue Chemistry Guidelines OPPTS 860.1500, 860.1520
- Acute Dietary Exposure Assessment OPP Policy, June 1996
- Chronic Dietary Exposure Assessment OPP Policy, ??? 1997
- Chemistry Science Advisory Council (CHEM SAC) Decisions

5.0 Specific Procedures

5.1 Regulatory Background

Section 408(b)(2)(E) of FFDCA as amended by FQPA requires that if EPA relies on **anticipated residues (ARs) or Actual Residues** to establish, modify, or leave in effect a tolerance, then EPA must require that data be provided five years after the tolerance decision is made to demonstrate that such residue levels have not changed.

Section 408(b)(2)(F) of the Act states that the Agency may use data on the actual percent of food treated or “**percent crop treated**” (PCT) in chronic dietary risk if such data are reliable and its use will not understate exposure for any significant population subgroup.

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Section 408(f) of FFDCA “Special Data Requirements” states that if EPA requires additional data or information to support a tolerance or exemption, it shall issue (a) a DCI, (b) a rule requiring testing or (c) an order in the FR.

5.2 Interpretations of FFDCA

5.2.1 **408(b)(2)(E)**--If EPA relies on anticipated or actual residue levels in establishing, modifying or leaving in effect a tolerance, it must call in data within five years **for all crops for which AR’s were used** for a pesticide. Such data will be used to demonstrate that the residue levels are not above the (anticipated) levels relied on. If the residues are higher, EPA shall reassess the risk posed by the pesticide and modify or revoke the tolerance as required to assure no adverse health concerns result from the pesticide.

5.2.2 **408(b)(2)(F)**--Whenever PCT has been used, EPA will obtain data through its usual sources (i.e., BEAD) within five years and determine whether the risks have increased unacceptably. EPA will not issue a data-call-in (DCI).

5.2.3 **408(f)**--EPA may use three methods to require data, but will use DCIs.

No rule is required for implementation of these provisions of the Act, but an Information Collection Request (ICR) covering the AR DCI data must be cleared through the Office of Management and Budget (OMB) before DCIs can be issued. A PR Notice will be issued to notify registrants and the public about FQPA’s requirements on AR/PCT and the process the Agency will follow.

5.2.4 FIFRA Section 18 Tolerances--Any tolerances established in conjunction with FIFRA Section 18s that use ARs and/or PCT are subject to FQPA. Data or information required to verify these tolerances are required to be submitted five years after their issuance unless EPA obtains and uses new information that either corroborates or changes the initial AR data. If a Section 18 tolerance is repeatedly renewed with little or no new information, data must be called in.

To obtain AR data for Section 18 exemptions, OPP may: (a) issue a letter requesting data from the main registrant (producer of the technical) at the same time that the Section 18 is issued; (b) place a notice in the initial Section 18 approval telegram (and in subsequent years) indicating that data are required to be submitted five years later or else a Section 18 will not be granted and the tolerance will be revoked (registrants would also be notified by letter of this requirement); or (c) both.

5.3 Definition of Terms Used in this Document

5.3.1 **Anticipated Residues** are estimates of the level of residues of a pesticide likely to be present on a given crop and are generally lower than tolerances. Data used for these estimates are

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based on:

1) *Field Trial Studies* designed to show what residue levels will be present in crops at harvest. These studies are conducted at maximum label rate and minimum pre-harvest interval, and are designed to show the maximum residues likely to be present. Field trial data can be used to project the residue amounts on treated crops and how various factors may affect those levels. Field trial data can therefore, be combined with percent crop treated data to produce a more realistic estimate of human exposure.

2) *Monitoring Data* which provide measurements of actual residues in/on commodities as they move in commerce. Monitoring data or actual residue data are collected by sampling a cross-section of a crop and it include treated and untreated commodities. Actual residue data reflects both the processes measured by field trial studies and the percent of the crop actually treated. Therefore, actual residue data for a given commodity would generally not be combined with either field trials data or percent crop treated information for that commodity in estimating human exposure. Actual residue measurements are taken on samples gathered as the commodities leave the farm (e.g., FDA Surveillance samples taken as close as possible to the point of production), when the food is in the general channels of distribution (e.g., USDA's PDP taken at food distribution centers), or at the retail level (e.g., EBDCs market basket survey). Actual residues are provided by:

- a) FDA Programs--Surveillance/Compliance Monitoring and Total Diet.
- b) USDA Programs-- AMS Pesticide Data Program and FSIS Monitoring Program (meat and poultry).
- c) Special Studies--FDA Total Diet Survey which show residues after consumer preparation or cooking of foods.

3) *Processing Studies* designed to determine the concentration or reduction of residues when the raw agricultural commodity is processed commercially.

4) *Degradation/Decline Studies* showing the degradation rates of pesticide residues.

5) *Livestock Feeding Studies and Nature of the Residue in Livestock* to identify the nature of the residue in the edible tissue of livestock and the transfer of these residues to meat, milk, poultry, and eggs. These studies are required when a pesticide is applied directly to livestock, to crops or crop parts used for feed, or when livestock premises are to be treated.

5.3.2 Percent Crop Treated means the scope of pesticide treatment for a crop expressed as a percentage. Percent crop treated information is useful for estimating exposure because it defines what segment of the crop is pesticide free.

5.4 Dietary Exposure

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Dietary exposure to pesticides in foods is estimated by multiplying the daily consumption of the food forms of a given commodity by the amount of pesticide residues on the food forms. Exposures based on tolerance levels are Theoretical Maximum Residue Contribution (TMRC) estimates. A TMRC is considered a “worst case” estimate because it assumes that the food contains residues at the tolerance level and that 100 percent of the crop is treated. If the TMRC exceeds the reference dose or poses an unacceptable lifetime cancer risk, EPA attempts to derive a more accurate estimate of residues likely to be present in foods (anticipated residues).

5.4.1 Tiered Approach to Estimating Dietary Exposure: In an attempt to conserve resources, the Agency developed a tiered process by which pesticide tolerance data (40 CFR 158.240) are refined to reflect pesticide residues in food as consumed (dinner-plate). This tiered approach flows from conservative to more refined assumptions as the risk management situation dictates. Dietary exposure estimates based on tolerance level residues (farm-gate) reflect a Theoretical Maximum Residue Contribution (TMRC) which overestimate actual dietary exposure. The best estimate of pesticide residues in food, as consumed, is termed the Anticipated Residue (AR) estimate. When estimating ARs the Agency uses all available data, therefore, reviewers must exercise considerable scientific judgment to derive anticipated residue estimates.

Attachment 1 summarizes applicability of the various tiers in estimating acute and chronic exposures.

5.5 Data Needed to Verify Anticipated Residues

Verification of the anticipated residues used in establishing a tolerance depends on the data source. Table 1 below addresses specific cases.

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Table 1. Data Needed to Verify Anticipated Residue Calculations

SOURCE OF DATA USED IN ANTICIPATED RESIDUES	DATA NEEDED TO CONFIRM ANTICIPATED RESIDUES 5 YEARS LATER
Monitoring data (PDP, FDA, FSIS, States, special monitoring [market basket, single serving, etc.]	Updated monitoring data are required. The registrant may use any of the publicly available sources used by the Agency. Data should reflect the time period since establishment of the tolerance. If data are not available from the above sources, then the registrant must conduct an appropriately designed monitoring study. The design of this study must be approved by the Agency.
Field Trials	The registrant must <u>EITHER</u> verify that the pesticide formulations, application rates, timing, intervals, geographic distribution of use, etc., have not changed <u>OR</u> provide field trial data that reflect any changes in the use pattern that may lead to increased residues.
Processing studies Reduction in residue data (washing, peeling, cooking, etc.)	The registrant must <u>EITHER</u> certify that commercial processing practices have not changed significantly <u>OR</u> provide new processing studies reflecting current commercial practices. A similar requirement applies to any study used to demonstrate reduction in residues between farm gate and consumption.
Livestock feeding studies and metabolism studies	Registrant must <u>EITHER</u> verify that the dietary burden calculations that were incorporated in the original AR derivation for meat, milk, poultry or eggs are still valid <u>OR</u> provide a new animal feeding study that reflects current feeding practices. Dietary burden calculations could change due to increased residue levels on feed items or from changes in the relative abundance or use of a particular feed item over time.

5.5.1 Hypothetical Scenario: A tolerance is established for a chemical already registered for use on ten food crops. Anticipated residues are developed for seven of ten previously registered crops to support registration of crop 11 as shown in Table 2.

Table 2. Data Sources Used to Support the Tolerance for “New Crop 11

TOLERANCES	DATA SOURCE	RESIDUE ESTIMATE	ANTICIPATED RESIDUE?
Old crop 1	Monitoring	Mean	Yes
Old crop 2	Monitoring	Mean	Yes
Old crop 3	Monitoring	Mean	Yes
Old crop 4	Monitoring	Mean	Yes
Old crop 5	Monitoring	Mean	Yes

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Old crop 6	Field trials	Mean	Yes
Old crop 7	Field trials	Mean	Yes
Old crop 8	Field trials	Tolerance	No
Old crop 9	Field trials	Tolerance	No
Old crop 10	Field trials	Tolerance	No
estimated residue consumption from crops 1-10 = 80% of RfD			
New crop 11	Field trials	Tolerance	No
estimated residue consumption from crops 1-11 = 90% of RfD			

In accordance with the interpretation in Section 5.2 above, the registrant has to verify that the ARs on crops 1 through 7 still support the tolerance on crop 11 after 5 years. Each individual AR for crops 1 through 7 must be confirmed with data similar to that originally used to derive the AR for that crop (see Table 1). This confirmation will be on a crop by crop basis. If the anticipated residue for any commodity exceeds the value relied on previously then a new dietary risk assessment will be necessary to determine if the tolerance on crop 11 needs to be altered or revoked.

5.6 Non-Detects

There are two possible explanations for residues reported as “not detected”: either the residues are for all practical purposes zero (e.g., pesticide was not applied) or the residues may be present at levels lower than the limit of detection (LOD) of the analytical method used. The Chem SAC recommendations for handling non-detects are as follows:

1. A true zero may be entered for non-detects if the percentage of samples reported as non-detects is equal or greater than the percent crop *not* treated. The number of samples entered as zeros should be directly proportional to the percent crop *not* treated. The reviewer should work closely with BEAD in selecting the appropriate percent crop treated figure (e.g., maximum, average, or other PCT figure).
2. A zero may be used to represent non-detects if metabolism studies, data at shorter PHIs, exaggerated rate data, etc. support this decision.
3. A value such as ½ LOD or ½ LOQ or the Lower Limit of Method Validation (LLMV) may be used. [LLMV: lowest concentration at which the method was validated. A LLMV could be higher than true LOQ.]

5.7 Documentation Requirements

Estimation of anticipated residues must be thoroughly documented. All HED documents transmitted to RD or SRRD that are concerned with either establishing, modifying, or leaving in effect a tolerance must contain the following information:

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- a. **Percent Crop Treated (PCT):** Indicate whether assumption of 100 percent crop treated is made or actual percent crop treated data were used. If PCT data were used, include the source of these data (e.g., for BEAD data, attach transmittal memorandum documenting years the PCT represent for each crop). Describe any assumptions made and actual PCT values used.
- b. **Dietary Exposure Assessment:** Must contain a clear and complete account of the basis for estimating dietary exposure. For each food form included in the assessment, indicate whether exposure was based on tolerance level residues or anticipated residues and whether PCT data were used.
- c. **Anticipated Residues:** If ARs were used, list actual numerical estimates used and the source of the estimate (i.e., FDA monitoring data, field trial data, processing studies, etc.) Document must fully describe all values, assumptions, and data manipulation used in deriving anticipated residues including use of default values (e.g., 1/2 LOD/LOQ for non-detects, 1/2 LOQ for BQLs, etc.). The sources of all data must be documented sufficiently that any interested party could repeat the calculations.

The HED recommended format for documentation of anticipated residues derived from field trials, monitoring data, and processing studies is provided in examples given in Attachment 2.

- d. **Dietary Exposure Assessments:** Must be documented in the form of a memorandum containing all of the elements found in the HED DEEM SOP (being prepared by DRES committee). Each memorandum will contain, at a minimum, a description of the following information:
 - a. Type of action (section 18, reregistration, new use, etc.).
 - b. Toxicological Information (RfD, data gaps, uncertainty factor, NOEL, carcinogenicity, etc), including reference to HED documents containing these data.
 - c. Residue Information (CFR references, PCT, AR data, concentration factors, etc.) including reference to HED documents containing these data.
 - d. Results and Discussion (refinements to the analysis, TMRC and ARC numbers, changes to concentration factors, population subgroups exceeding 100% RfD, commodity contribution analysis if RfD exceeds 100%.
 - e. Names of preparer and reviewer, date, and file location.
 - f. For Monte Carlo runs attach input and output files.

Attachment 1

Tiered Approach to Estimating Dietary Exposure *

	Dietary Assessment
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	Acute		Chronic (Carcinogenic and non-carcinogenic)
	Single Serving	Blended	Single Serving/Blended
Tier 1	<ul style="list-style-type: none"> ▷Tolerance ▷100% CT 	<ul style="list-style-type: none"> ▷Tolerance ▷100% CT 	<ul style="list-style-type: none"> ▷Tolerance ▷100% CT
Tier 2	<ul style="list-style-type: none"> ▷Tolerance ▷100%CT 	<ul style="list-style-type: none"> ▷Average residue from field trials ▷100% CT 	<ul style="list-style-type: none"> ▷Tolerance ▷Adjust for %CT
Tier 3	<ul style="list-style-type: none"> ▷Entire distribution of data from field trials ▷Adjust for %CT 	<ul style="list-style-type: none"> ▷Average residue from field trials ▷Adjust for %CT ▷Processing factors <li style="text-align: center;">-or- ▷Entire distribution of monitoring data ▷100 %CT. ▷Processing factors 	<ul style="list-style-type: none"> ▷Average residue from field trials ▷Adjust for %CT ▷Processing factors <li style="text-align: center;">-or- ▷Average residue of monitoring data ▷Adjust for %CT ▷Processing factors
Tier 4	<ul style="list-style-type: none"> ▷Single Serving Market basket survey ▷Cooking ▷Residue decline ▷Residue degradation 	<ul style="list-style-type: none"> ▷Use monitoring data directly ▷Cooking ▷Residue decline ▷Residue degradation 	<ul style="list-style-type: none"> ▷Single Serving Market basket survey ▷Cooking ▷Residue decline, ▷Residue degradation

* For meat, milk, poultry, and eggs, if monitoring data are not available, 1) calculate the dietary burden using anticipated residues for feedstuffs; 2) extrapolate from livestock feeding studies

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Attachment 2

XYZ (Chemical # 000001)--Anticipated Residues Derived from Monitoring Data

Commodity	Data Source	No. of Samples	No. of Detects	% Detects	LOD ppm	LOQ ppm	% Crop Treated	Max. Residue	Average Residue	95th Percentile
caneberries blackberries boysenberries dewberries loganberries raspberries	FDA 92-96	158	19	12		0.02	55	0.204	0.0089	0.02
blueberries	FDA 92-96	176	10	5.7		0.02	80	0.08	0.0093	T
cranberries	FDA 92-96	69	1	1.4		0.02	7	0.02	0.0008	ND
	FODC 92-96	111	0	0.0		0.02	7	ND		ND
grapes	PDP 95-96	1215	0	0.0		0.023	1	ND	0.0001	ND
strawberries	FDA 92-96	644	78	12.1		0.02	28	0.28	0.0133	0.08

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XYZ (Chemical # 000001)--Anticipated Residues Derived from Monitoring Data (continued)

Commodity	Data Source	No. of Samples	No. of Detects	% Detects	LOD ppm	LOQ ppm	% Crop Treated	Max. Residue	Average Residue	95th Percentile
grapefruit	FDA 92-96	133	0	0.0		0.02	1	ND	0.0001	ND
orange	PDP 95-96	1209	6	0.5		0.037	1	0.028	0.0002	ND
orange juice	PDP 97	604	0	0.0		0.02	1	ND	0.0001	ND
apple	PDP 95-96	1723	0	0.0		0.037	15	ND	0.003	ND
apple juice	PDP 96	177	1	0.6		0.023	15	<0.017	0.002	ND
tomatoes	PDP 96	174	0	0.0		0.030	2	ND	0.0003	ND
whole grain wheat	PDP 95-96	940	275	29.3		0.01	100	2.874	0.065	0.305
wheat flour	FDA 92-96	113	79	69.9		0.02	100	1.056	0.0631	0.247
milk	PDP 96	558	0	0.0		0.0033	--	ND	0.0017	ND

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XYX (Chemical # 000001)--Anticipated Residues Derived from Field Trial Studies

Crop	Average Residue	Maximum Residue	PCT	Anticipated Residue	Source of Data	Review Reference
Macadamia nuts	0.05	0.1	6	0.00300	MRID 44076801	DP Barcode
Chestnuts	0.261	0.632	100	1.00000	MRID 44478401	DP Barcode
Walnuts	0.05	0.10	9	0.00450	MRID 44383301	DP Barcode
Figs	0.203	0.387	6	0.01220	MRID 44061201	DP Barcode
Guava	0.159	0.48	100	0.15900	MRID 44391501	DP Barcode
Passion Fruit	0.0564	0.121	100	0.05640 or 8??	MRID 44472801	DP Barcode

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XYZ (Chemical # 000001)--Anticipated Residues Reflecting Processing Factors

Crop	Processed Form	Concentration or Dilution Factor	Source of Data	Review Reference
Grapes	Juice	0.1X	MRIDXXXXXXXX	DP Barcode
	Raisins	0.4X	MRIDXXXXXXXX	DP Barcode
Citrus Fruits	Juice	0.06X	MRIDXXXXXXXX	DP Barcode
Apples	Juice	0.13X	MRIDXXXXXXXX	DP Barcode
Tomatoes	Juice	0.03X	MRIDXXXXXXXX	DP Barcode
	Puree	0.6X	MRIDXXXXXXXX	DP Barcode
	Catsup	0.8X	MRIDXXXXXXXX	DP Barcode
Rice	Milled	0.02X	MRIDXXXXXXXX	DP Barcode
Corn	Oil	0.01X	MRIDXXXXXXXX	DP Barcode
Cottonseed	Oil	0.007X	MRIDXXXXXXXX	DP Barcode
	Meal	0.07X	MRIDXXXXXXXX	DP Barcode
Mint	Oil	12.7X	MRIDXXXXXXXX	DP Barcode

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Methidathion (PC Code 100301)--Anticipated Residues Derived from Monte Carlo Assessments

Crop/Food Form	Data source	# of Samples	PCT	Residues found (Total non-zeros)	Total zeros	Value Entered for NDs	Comments
orange juice	PDP-1997	692	100	10	--	--	
apples	PDP-1998	100	3	3	97	½ LOQ	
pears	PDP-1997	100	11	11	89	½ LOQ	
apple juice	PDP- 1997	683	100		--	½ LOQ	
apple juice	PDP -1996	177	100				
olives	FDA?	2	2	2	98	½ LOQ	
oranges	Field trial	11	11	11	89	--	MRID# 44491001 also used for citron & kumquats maximum value 3.4 ppm

Food Form (RAC/Processed)	year/ data source	# of data points	Conc. Range	Average	Tolerance/ food/feed additive	# of non- detects	LOD	LOQ	Data Handling
grapefruit	1996/field trials	10	0.76-3.76	1.55	4				
dried pulp					8				