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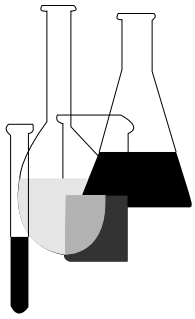
Residue Chemistry Test Guidelines

OPPTS 860.1520
Processed Food/Feed



INTRODUCTION

This guideline is one of a series of test guidelines that have been developed by the Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency for use in the testing of pesticides and toxic substances, and the development of test data that must be submitted to the Agency for review under Federal regulations.

The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has developed this guideline through a process of harmonization that blended the testing guidance and requirements that existed in the Office of Pollution Prevention and Toxics (OPPT) and appeared in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs (OPP) which appeared in publications of the National Technical Information Service (NTIS) and the guidelines published by the Organization for Economic Cooperation and Development (OECD).

The purpose of harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the data requirements of the U. S. Environmental Protection Agency under the Toxic Substances Control Act (15 U.S.C. 2601) and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136, *et seq.*).

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OPPTS 860.1520 Processed food/feed.

(a) **Scope.** (1) **Applicability**. This guideline is intended to meet testing requirements of both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, *et seq.*) and the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 301, *et seq.*).

(2) **Background**. The source material used in developing this harmonized OPPTS test guideline is OPP 171–4, Results of Tests on the Amount of Residue Remaining, Including a Description of the Analytical Methods Used (Pesticide Assessment Guidelines, Subdivision O: Residue Chemistry., EPA Report 540/9–82–023, October 1982). This guideline should be used in conjunction with OPPTS 860.1000, Background.

(b) **Purpose.** Processing studies are required to determine whether residues in raw commodities may be expected to degrade or concentrate during food processing. If residues do concentrate in a processed commodity, a food or feed additive tolerance must be established under section 409 of the FFDCA (or a section 701 Maximum Residue Limit (MRL) in some cases). However, if residues do not concentrate in processed commodities, the tolerance for the raw agricultural commodity (RAC) itself applies to all processed food or feed derived from it.

(c) **Concentration of residues on processing.** (1) Whenever there is a possibility of residue levels in processed foods/feeds exceeding the level in a RAC, processing data are required. Examples of processed foods/feeds in which residues may concentrate are apple juice and apple pomace, the hulls, meal, and refined oil from cottonseed, or the sugar, dried pulp and molasses from sugar beet roots. A list of processed byproducts is contained in Table 1 of OPPTS 860.1000, Background.

(2) Processing studies should simulate commercial practices as closely as possible. RAC samples used in processing studies should contain field-treated quantifiable residues, preferably at or near the proposed tolerance level, so that concentration factors for the various byproducts can be determined. As discussed in paragraph (f)(3) of this guideline, this may require field treatment at exaggerated application rates to obtain sufficient residue levels for processing studies. Processing studies utilizing spiked samples are not acceptable, unless it can be demonstrated that the RAC residue consists entirely of a surface residue.

(3) Only one processing study is required for each crop in Table 1 of OPPTS 860.1000 having a processed commodity. However, it is advisable to have multiple samples of the RAC and processed commodities in the study. As stated in paragraph (f)(2) of this guideline, if multiple processing studies are available for a given crop, the Agency will use the average concentration factor obtained across these studies. In some cases the requirement for a processing study may be waived based on field trial

data for the RAC reflecting exaggerated application rates. This is discussed in more detail in paragraph (f)(3) of this guideline.

(4) The total toxic residue should be measured in the raw agricultural commodity at the time processing is initiated and in all processed commodities of the crop listed in Table 1 of OPPTS guideline 860.1000. With the exception of the small grains, the Agency will not normally translate data between crops. In the case of small grains, a processing study on wheat satisfies the requirement for studies on barley, buckwheat, millet, oats and rye if the pesticide is applied to all these crops in a similar manner and comparable residue levels occur in the grains.

(5) Unless the processed commodities are analyzed within thirty days of their production, data demonstrating the stability of residues in representative processed commodities during storage are required as described in OPPTS guideline 860.1380.

(6) If the processing studies indicate that residues concentrate on processing, then a food additive petition, including a food additive regulation proposal, is normally required as specified by section 409 of the FFDCA. However, for a processed food or feed that is not ready-to-eat, an MRL may need to be proposed under section 701 of the FFDCA. This is explained in more detail in paragraph (f)(5) of this guideline.

(d) **Reduction of the residue level on processing.** In those cases where the assumption of tolerance level residues occurring in commodities results in unacceptable exposure, then the petitioner has the option of submitting data on food prepared for consumption. The Agency will take into account data on washing, trimming, cooking, peeling or processing to the extent that these procedures are used on specific commodities. Although the lower levels of residues resulting from such processes may be used in the risk assessment, the tolerance will still be set on the commodity as it travels in interstate commerce. Of course, if these data indicate that residues concentrate in some fractions while decreasing in others, both the higher and lower residue levels will be used in the risk assessment. The Agency will also take into account the wide variation in techniques used to prepare food. For example, if cooking completely destroys the residue on a vegetable, the Agency will use, at a maximum, the limit of quantitation (LOQ) in the cooking study as the residue level for cooked vegetables. The Agency will also use the consumption of uncooked vegetables and the tolerance level to estimate the exposure from uncooked vegetables.

(e) **Maximum theoretical concentration factors.** (1) This paragraph addresses maximum theoretical concentration factors for use in determination of the exaggerated application rate needed for field trials on commodities which can be processed. The use of exaggerated rate studies is discussed in more detail in paragraph (f)(3) of this guideline. The following Table 1 provides a listing of maximum theoretical concentration factors.

A secondary use of this list could be for worst case dietary exposure assessment, when experimental processing data are unavailable.

Table 1.—Maximum Theoretical Concentration Factors by Crop

Crop	Maximum Concentration Factor
Apples	>14×*
Barley	8×
Beets, sugar	>20×*
Canola	3×
Citrus	1000×
Coconut	3×
Coffee	4.5×
Corn	25×
Cottonseed	6×
Figs	3.5×
Grapes	5×*
Mint (peppermint, spearmint)	330×
Oats	8×**
Olive	10×
Peanuts	3×
Pineapple	4×
Potatoes	5×
Plums (prunes)	3.5×
Rapeseed	2×
Rice	8×
Rye	10×
Safflower	9×
Soybeans	12×
Sugarcane	>20×*
Sunflower	4.5×
Tomatoes	5.5×*
Wheat	8×

*Experimental factor
**Based on factor for wheat

(2) The list is not all inclusive as factors are not available for all processed commodities listed in Table 1 of OPPTS 860.1000. In addition, some processed commodities may have greater potential for concentration than those processed commodities for which factors were calculated. For those commodities for which higher concentrations are expected, the Agency has tabulated some experimental concentration factors, by comparing proposed and established food/feed additive tolerances to the proposed and established tolerances for the RAC. Additional factors may be added or updated in the future as further information becomes available.

(3) There are two types of processes for which maximum theoretical concentration factors can easily be calculated. The first type is where the concentration is based on the loss of water during processing. In this case, the theoretical concentration factor is the ratio of the percent of dry matter in the processed commodity to the percent of dry matter in the RAC. For example, grapes contain 18 percent dry matter while raisins contain 85 percent dry matter. The theoretical concentration factor for the processing of grapes into raisins is 85/18 or 4.7×. The second type of process is that in which a RAC is separated into components, such as the processing of corn grain into corn oil. In this case, the theoretical concentration factor is 100 percent divided by the percentage of the processed commodity in

the RAC. Corn grain may contain as little as 4 percent corn oil. The theoretical concentration factor for processing of corn into oil then is 100/4, or 25×.

(4) In cases where a crop had multiple processed fractions, only the fraction having the highest maximum theoretical concentration factor is listed in Table 1 (see paragraph (e)(1) of this guideline). In some cases, only typical yields were available for a particular RAC, particularly for grains. A factor was still calculated, but may not actually be the maximum theoretical concentration factor. The following Table 2 shows calculations for those commodities where concentration is based on loss of water, Table 3 shows calculations for those commodities where concentration is based on separation into components, and Table 4 is a tabulation of experimentally determined factors obtained by comparing proposed and established food/feed additive tolerances to the proposed and established tolerances for the RAC. A bibliography for the tables is given in paragraph (e)(5) of this guideline.

Table 2.—Theoretical Concentration Factors Based on Loss of Water

Crop	percent dry matter	Factor	Reference
Figs	22		PAM I, sec. 202.12
dry figs	76	3.5	PAM I sec., 202.12
Grapes	18		Harris Guide
raisins	85	4.7	Harris Guide
Potatoes	20		USDA
dried (flakes, granules)	93	4.7	USDA
Plums	21		PAM I, sec. 202.12
prunes	72	3.4	PAM I, sec. 202.12
Tomatoes	6		p. 311, Commercial Vegetable Processing, 2nd Ed.
puree	8.5	1.4	p. 272, Commercial Vegetable Processing, 2nd Ed.
paste	33	5.5	p. 277, Commercial Vegetable Processing, 2nd Ed.

Table 3.—Theoretical Concentration Factors Based on Separation into Components

Crop	Minimum percent of whole	Factor	Reference
Barley grain			
bran	13	7.7	based on wheat bran
pearled	82	1.2	p. 426, Principles of Field Crop Production
Beets, sugar			
sugar	8	12.5	Advances in Sugar Beet Production
molasses			
dried pulp			
Canola			
meal	52	1.9	p. 259, by difference, CRC Handbook of Processing and Utilization in Agriculture
oil	33	3.0	p. 259, CRC Handbook of Processing and Utilization in Agriculture

Table 3.—Theoretical Concentration Factors Based on Separation into Components—Continued

Crop	Minimum percent of whole	Factor	Reference
Citrus			
peel	30	3.3	p. 1391, Considine Foods and Food Production Encyclopedia
oil	0.1	1000	PAM I, sec. 202.12
pulp, dehydrated			
juice	50	2	p. 1387, Considine Foods and Food Production Encyclopedia
Coconut			
oil	35	2.9	PAM I, sec. 202.15
copra (dried meal)		2.1	DRES (from USDA Handbook No. 102)
Coffee			
roasted bean	1.2	18 percent loss in weight in roasting	p. 459 Considine
instant		4.4	PP no. 0E3875-based on weights in processing study
Corn grain			
oil	4	25.0	p. 243, Corn, Culture, Processing, Products
Cottonseed			
hulls	26	3.8	p. 187, CRC Handbook of Processing and Utilization in Agriculture
meal	45	2.2	p. 187, CRC Handbook of Processing and Utilization in Agriculture
oil	16	6.3	p. 187, CRC Handbook of Processing and Utilization in Agriculture
Grapes			
juice	82	1.2	Harris Guide
Mint			
oil	0.3	333	15 mL oil from 10 lb hay
Oats			
flour			
rolled oats	70	1.4	p. 577-8, Cereal Crops
Olive oil			
oil	10	108	p. 1372, Considine Foods and Food Production Encyclopedia
Peanuts			
meal	46	2.2	p. 139, by difference, see p 293, Peanuts:....
oil	36	2.8	PAM I, sec. 202.25
Pineapple			PP no. 6F0482
process residue	26	3.8	
juice			
Potatoes			
processed waste	25	4.0	NorthWest Food Processors Association
Rapeseed			
meal	52	1.9	p. 259, by difference, CRC Handbook of Processing and Utilization in Agriculture
Rice grain (rough rice)			
hulls	20	5.0	pp. 649, 652, Cereal Crops
bran	13	7.7	p. 649, 652, Cereal Crops
Rye grain			
bran	10	10.0	p. 244-5, CRC Handbook of Processing and Utilization in Agriculture
flour			
Safflower			
meal	11	9.1	p. 114, CRC Handbook of Processing and Utilization in Agriculture

Table 3.—Theoretical Concentration Factors Based on Separation into Components—Continued

Crop	Minimum percent of whole	Factor	Reference
oil (safflower)	30	3.3	p. 114, CRC Handbook of Processing and Utilization in Agriculture
Soybeans			
hulls	9	11.3	MRID No. 424482-03, Appendi× B, p67
meal	46	2.2	CBRS No. 10541, D. Miller, 1/29/93
oil	8	12.0	CBRS No. 10541, D. Miller, 1/29/93
Sugarcane			
molasses			
sugar	8.5	11.8	p. 426, Principles of Field Crop Production
Sunflower			
meal	22	4.5	p. 146, by difference, CRC Hand book of Processing and Utilization in Agriculture
oil	40	2.5	p. 146, CRC Hand book of Processing and Utilization in Agriculture
Tomatoes			
juice	70	1.4	p. 303, Commercial Vegetable Processing, 2nd. Ed.
Wheat grain			
bran	13	7.7	p. 2125, Considine
flour	72	1.4	pp. 295-6, Cereal Crops
shorts	12	8.3	pp. 295-6, Cereal Crops

Table 4.—Maximum Observed (Experimental) Concentration Factors

Crop	Maximum Concentration Factor [1]
apple pomace	14×
sugar beet pulp, dry	20×
sugarcane molasses	20×

[1] These factors are based on a comparison of proposed and established food additive tolerances to the proposed and established tolerances on raw agricultural commodities.

(5) The following is a bibliography for Tables 1 through 4.

Pesticide Analytical Manual, Volume I (PAM I), 1994, Food and Drug Administration.

Agriculture Handbook No. 8, Composition of Foods: Raw, Processed, prepared, U. S. Department of Agriculture, Agricultural Research Service, B. K. Watt, and A. L. Merrill, December, 1963.

CRC Handbook of Processing and Utilization in Agriculture, Volume II, Part 2 Plant Products, I. A. Wolff, ed., CRC Press, Boca Raton, FL 1983.

Foods and Food Production Encyclopedia, D. M. Considine, and G. D. Considine, eds., Van Nostrand Reinhold, New York, 1982.

Commercial Vegetable Processing, 2nd Edition, ed. B. S. Luk, and J. G. Woodroof, Avi/Van Nostrand Reinhold, New York, 1988.

Peanuts: Production, Processing, Products, 2nd Edition, J. G. Woodroof, Avi Publishing, Westport, CT, 1973.

Corn: Culture, Processing, Products, Ed. G. E. Inglett, Avi Publishing, Westport, CT, 1970.

Oats: Chemistry and Technology, ed. F. H. Webster, American Association of Cereal Chemists, Inc., St. Paul, MN 1986.

Advances in Sugar Beet Production: Principles and Practices, eds., R. T. Johnson, et. al., Iowa State University Press, Ames, IA 1971.

Harris Guide.

Feeds & Nutrition--Complete, First Edition, Ensminger, M. E., and C. G. Olentine, Jr., Ensminger Publishing Co., Clovis, CA 1978.

Cereal Crops, Leonard, W. H., and J. H. Martin, Macmillan Co., New York, 1963.

Principles of Field Crop Production. 3rd. Edition, Martin, J. H., W. H. Leonard, and D. L. Stamp, Macmillan, New York, 1976.

(f) **Determining the need for food/feed additive tolerances**—(1) **RAC residue value.** (i) The Agency will consider using some average residue value from field trials if it can be determined that there is sufficient mixing during processing such that variation among individual samples from a field will be substantially evened out. It has been stated that ‘‘* * * * * the most relevant ‘average’ residue value from crop field trials is the highest average residue value from the series of individual field trials * * * *.’’ This value is sometimes referred to as the HAFT (highest average field trial). Other average values (e.g. average of all field trials) may be considered if the circumstances involved in processing of the crop warrant. Such an example would be where processing is likely to involve blending of crop from across a regional or national market.

(ii) As a result of this policy, it is necessary to determine the HAFT for each RAC for which a processing study has shown concentration of residues. For each field trial reflecting the maximum residue use (i.e. maximum number and rate of application, minimum preharvest interval) and considered acceptable for determining the section 408 of FFDCA tolerance (i.e. values discarded for reasons such as contamination should not be included), residue values for all samples at that site reflecting that use should be averaged. (NOTE: If residues were corrected for low method recoveries or for losses during storage in order to determine the tolerance, the corrected values should also be used in this exercise.) The highest such average value is the HAFT and is to be used to calculate the maximum expected residue in processed commodities. For field trials in which only one sample per site reflects the maximum residue use no averaging can be done and the highest individual residue value becomes the HAFT.

(2) **Multiple processing studies.** (i) Whenever more than one processing study has been conducted for a particular pesticide on a given RAC, the average concentration factor should be used for each processed commodity when determining the need for section 409 tolerances (or section 701 MRLs under paragraph (c)(6) of this guideline). Similarly, if multiple samples or subsamples are analyzed within a processing study, the average residue value should be used for each commodity as opposed to using

the lowest value from the RAC samples and the highest value for the processed fraction samples, which would result in the highest concentration factors. When averaging concentration factors across studies, factors which exceed the theoretical maximum should be lowered to the latter for averaging purposes. In no instance should a section 409 tolerance (or section 701 MRL) be based on a concentration factor greater than the theoretical maximum. If only one processing study has been conducted and the theoretical concentration factor has been exceeded, the section 409 or section 701 residue level should be based on the factor (if available) listed in Tables 1 through 4 of this guideline.

(ii) As stated in paragraph (c)(2) of this guideline, processing studies should reflect actual commercial practices. If several studies are available and a step (e.g. washing) that is routinely used in the processing of that RAC is omitted, it may be inappropriate to include that study in the calculation of the average concentration factor.

(3) **Use of exaggerated rate studies.** (i) The Agency encourages use of field trials with exaggerated application rates in cases where residues near or below the analytical method's LOQ are expected in the RAC from the maximum registered rate (1×). For purposes of this discussion, pesticide uses can be divided into those which result in quantifiable residues in the RAC and those which do not. The former would have section 408 tolerances set above the LOQ, while the latter would usually have tolerances set at the LOQ. In either case, if possible, processing studies should use RAC samples which contain quantifiable residues.

(ii) For uses which result in quantifiable residues in the RAC from the registered application rate, exaggerated rate applications are not needed to generate RAC samples for processing if all field trials lead to residues well above the LOQ. However, if residues below or near the LOQ are observed in some field trials, it is advisable for an exaggerated application rate to be used to generate RAC samples for the processing study. Regardless of whether exaggerated application rates are used, if a section 408 tolerance is based on the presence of quantifiable residues and concentration of residues is observed in a processed commodity, that concentration factor will be used in conjunction with the HAFT or other applicable average value and other relevant factors (e.g. variability of the analytical method) to determine the need for a section 409 tolerance (or section 701 MRL). In other words, the concentration factor will *not* be adjusted for the use of exaggerated rates in cases where quantifiable residues are observed in the RAC from the registered use.

(iii) In those cases where *all* RAC samples from the field trials show residues below the LOQ and the residue data cover *all* significant growing regions for the crop as delineated in OPPTS 860.1500, it may be possible to waive the processing study and conclude that section 409 tolerances (or section 701 MRLs) are not needed based on the results of field trials

conducted at exaggerated application rates. With the exception of mint and citrus, if exaggerated rate data are available and these field trials result in no quantifiable residues in the RAC, no processing study and section 409 tolerances are required provided that the rate was exaggerated by at least the highest theoretical concentration factor among all the processed commodities derived from that crop *or* 5×, whichever is less. Processing studies will be needed for citrus and mint in virtually all cases due to the extremely high potential concentration factors for citrus oil (1,000×) and mint oil (330×).

(iv) If no quantifiable residues are found in the RAC from the maximum registered rate, but the exaggerated rate does produce quantifiable residues, the latter samples should be processed and residues measured in the appropriate commodities. Any residues still above the LOQ in the processed commodities should be adjusted for the degree of exaggeration. These adjusted residues should then be compared to the LOQ for the RAC. If the adjusted residues are greater than or equal to twice the LOQ, a section 409 tolerance (or section 701 MRL) is needed. Due to the variability associated with an analytical method near its LOQ, a food additive tolerance (or section 701 MRL) will not normally be established for residues less than twice the LOQ. For example, consider a field corn RAC tolerance set at 0.05 ppm (LOQ) and residues of 0.08 ppm being found in the RAC and 0.30 ppm in the oil following a 5× application rate. Adjusting for the 5× rate, oil residues would be 0.06 ppm, which is less than twice the LOQ. Therefore, a section 409 tolerance is not necessary. However, if the oil residues were 1.0 ppm, a section 409 tolerance (or perhaps section 701 MRL) at 0.20 ppm (1.0 ppm/5) would be necessary.

(v) One additional scenario needs to be discussed regarding use of exaggerated rates. In some cases no quantifiable residues may be found in the RAC, but the exaggerated rate is less than the maximum theoretical concentration factor (or 5×, whichever is less) due to phytotoxicity limitations. In these instances a decision will be made case-by-case as to the need for a processing study. If a processing study is deemed necessary, any quantifiable residues in processed fractions would be adjusted for the degree of exaggeration as explained in the previous paragraph. Some of the factors to consider when determining if the processing study is needed include how close the degree of exaggeration comes to the theoretical factor (or 5×, whichever is less) and whether *detectable* residues (i.e. greater than limit of detection but less than LOQ) are found in any RAC samples. Another consideration would be whether the pesticide is likely to be present on a specific portion of the RAC based on when it is applied and/or its ability to translocate. For example, a pesticide applied late in the growing season would be more likely to be on the surface of a fruit and have greater potential to concentrate in pomace than one applied only at the bloom stage or earlier.

(4) **Impact of Ready-to-Eat (RTE)**. (i) The classification of a processed food as RTE or *not* RTE will determine whether or not the possibility of setting a section 701 MRL needs to be explored as discussed under paragraph (f)(5) of this guideline. Until recently, the Agency has considered any food available for sale as being ready-to-eat. The Agency now holds that RTE food has a common sense meaning of food which is consumed without further preparation and will apply this interpretation in future actions. Therefore, food should now be considered ''ready-to-eat'' if it consumed ''as-is'' or is added to other RTE foods (e.g. condiments).

(ii) The Agency also realizes that application of this definition of RTE may be difficult in many instances. The following processed foods are examples of not-ready-to-eat: mint oil, citrus oil, guar gum, and dried tea. Examples of clearly RTE foods are raisins, olives, and potato chips. Vegetable oils are an example of foods not so easily characterized under this RTE standard. The Agency is presently analyzing information on food consumption and mixing of livestock feeds in order to classify processed commodities with respect to RTE. As such decisions are made, they will be made available to the public.

(5) **Determining the need for section 409 tolerances or section 701 MRL's.** (i) The Agency will establish food/feed additive tolerances (FATs) under section 409 of the FFDCA for processed foods or feeds that *are* classified as RTE if residues in those processed commodities are likely to exceed the corresponding section 408 tolerances. Therefore, for an RTE food such as raisins, the concentration factor (taking into account multiple processing studies and exaggerated rates, if applicable) should be multiplied by the HAFT (or other applicable average value) and that value compared to the RAC tolerance. If that number is appreciably higher than the section 408 tolerance, a food/feed additive (section 409) tolerance will be needed. The judgment as to ''appreciably higher'' will need to take into account how close the residue level is to the LOQ of the analytical method. If residues in the processed food are less than twice the LOQ, a section 409 tolerance is normally not needed. On the other hand, when residues in the processed food (i.e. concentration factor times HAFT) are significantly above the LOQ, a section 409 tolerance will normally be needed if those residues are approximately 1.5× the section 408 tolerance (or higher). For situations in which the processed food/feed residues are close to that level (e.g. 1.3 to 1.7× those in the RAC), all relevant information including variability in recovery data will be considered by the Agency when assessing the need for food/feed additive tolerances.

(ii) The procedure is more complex for processed foods or feeds that are *not* RTE (nRTE). If residues in an nRTE processed food exceed the section 408 tolerance, residues in the RTE forms of those foods/feeds will need to be determined and then compared to the section 408 tolerance. If the residues in the RTE (i.e. mixed/diluted) form do not exceed the RAC tolerance, the Agency will establish an MRL on the nRTE processed

commodity under section 701 of the FFDCA. On the other hand, if residues in the RTE (mixed/diluted) form still appreciably exceed those in the RAC, a food/feed additive tolerance will be established for the NRTE processed commodity under section 409 of the FFDCA.

(iii) In order to determine whether residues in the RTE (mixed/diluted) forms of nRTE processed foods/feeds exceed those in the RAC, the Agency will develop dilution factors. These will be based on the least amount of dilution that may occur for the nRTE food. For example, flour, assuming it is classified as nRTE, is likely to have a relatively low dilution factor based on its use in preparation of commodities such as crackers, bagels, and tortillas. Dried tea, on the other hand, is likely to have a large dilution factor based on the relative weight of water used to brew tea. At this time there is no list of dilution factors. As these factors are derived, the Agency will announce them to the public periodically.

(iv) The procedure for assessing nRTE processed commodities is as follows. The concentration factor (accounting for multiple processing studies and exaggerated rates, if necessary) is multiplied by the HAFT (or other applicable average value) to determine residues in the nRTE processed food. If the residue in the nRTE food does not appreciably exceed the section 408 tolerance, neither a section 409 tolerance nor section 701 MRL is needed. If the residue in the nRTE processed food does appreciably exceed the RAC tolerance, that residue should be divided by the dilution factor to determine the residue level in the RTE form. If the residue in the RTE (mixed/diluted) food is basically equal to or less than the section 408 tolerance, a section 701 MRL is needed for the nRTE processed commodity. If the residue in the RTE (mixed/diluted) food still appreciably exceeds the section 408 tolerance, a section 409 (i.e. food or feed additive) tolerance is needed for the nRTE processed commodity.

(v) This procedure can be illustrated by some examples using mint and the nRTE food mint oil. The assumption is made that for three different pesticides that the HAFT value is 8.0 ppm and that the RAC tolerance is 10 ppm. The assumption is also made that the dilution factor for mint oil is 160 for its use in preparation of RTE foods. Pesticide A is observed to concentrate 1.3× in mint oil. The concentration factor times the HAFT is equal to 10.4 ppm, which is not appreciably higher than the RAC tolerance of 10 ppm. Neither a section 409 tolerance nor section 701 MRL is needed for the mint oil. Pesticide B is found to concentrate 40× in mint oil. The concentration factor (40) times the HAFT (8.0 ppm) is qual to 320 ppm, well above the RAC tolerance of 10 ppm. The residues in the RTE (mixed/diluted) food are then calculated to be 2 ppm by dividing the mint oil residue of 320 ppm by the dilution factor of 160. The 2 ppm residue in the RTE food is below the 10 ppm RAC tolerance. Therefore, a section 701 MRL of 320 ppm should be established for the nRTE mint oil. Pesticide C is found to concentrate 320× in mint oil. The concentration factor (320) times the HAFT (8.0 ppm) is 2,560 ppm, which

is well above the RAC tolerance of 10 ppm. The residues in the RTE food are then calculated to be 16 ppm by dividing the mint oil residue of 2,560 ppm by the dilution factor of 160. The 16 ppm in the RTE (mixed/diluted) food appreciably exceeds the 10 ppm RAC tolerance. Therefore, a section 409 or food additive tolerance is needed for mint oil at 2,560 ppm (or more likely at 2,500 ppm considering significant figures).

(g) **Data report format.** The following describes a suggested format for a study report, item by item. However, other formats are also acceptable, provided that the information described this paragraph is included.

(1) *Title/cover page*. Title page and additional documentation requirements (i.e. requirements for data submission and procedures for claims of confidentiality of data if relevant to the study report) should precede the content of the study. These requirements are described in PR Notice 86–5 (see paragraph (h)(5) of this guideline).

(2) *Table of contents*.

(3) *Summary/introduction*.

(4) *Materials*—(i) *Test substance.* (A) Identification of the pesticide formulated product used in the field trial from which the RAC used in the processing study was derived, including the active ingredient therein, or if fortified RAC samples were used in the processing study, identity of the fortifying substances.

(B) Identification and amount of residues in experimentally treated RAC samples at the time the processing study is initiated.

(C) Any and all additional information petitioners consider appropriate and relevant to provide a complete and thorough description and identification of the test substances used in the processing study.

(ii) *Test commodity*. (A) Identification of the RACs (crop/type/variety) and the specific crop parts used in the processing study.

(B) Sample identification (source of samples, field trial identification number; control or weathered residue sample, coding and labeling information (should be the same as or cross-referenced to the sample coding/labeling assigned at harvest)).

(C) Treatment histories (pesticides used, rates, number of applications, preharvest intervals (PHIs), etc.) of the RAC samples used in the processing study.

(D) The developmental stages, general condition (immature/mature, green/ripe, fresh/dry, etc.) and sizes of the RAC samples used in the processing study.

(E) Any and all additional information the petitioner considers appropriate and relevant to provide a complete and thorough description of the RACs used in the processing study.

(5) *Methods*—(i) *Experimental design.* For example:

(A) Number of test/control samples.

(B) Number of replicates.

(C) Residue levels in the RACs to be used.

(D) Representativeness of test commodities to the matrices of concern, etc.

(ii) *Test procedures*—(A) Fortification (spiking) procedure, if used (detail the manner in which the test compounds were introduced to the RACs).

(B) A description of the processing procedure used and how closely it simulates commercial practice. Quantities of starting RAC and of resulting processed commodities.

(C) A description of the methods of residue analysis (see OPPTS 860.1340, Residue analytical method).

(D) A description of the means of validating the methods of residue analysis (see OPPTS 860.1340).

(E) A description of any storage stability validation studies that may have been performed (see OPPTS 860.1380, Storage stability data).

(6) *Results/discussion*—(i) *Residue results.* (A) Raw data and correction factors applied, if any.

(B) Recovery levels.

(C) Storage stability levels, if applicable.

(D) Direct comparison of residues in the RAC with those in each processed product or processing fraction derived from that sample, etc.

(ii) *Statistical treatments.* Describe tests applied to the raw data.

(iii) *Quality control.* Include if not covered elsewhere. Describe control measures/precautions followed to ensure the fidelity of the processing study.

(iv) *Other.* Constituting any and all additional information the petitioner considers appropriate and relevant to provide a complete and thorough description of the processing study or studies.

(7) *Conclusions*. Discuss conclusions that may be drawn concerning the concentration/reduction of the test compounds in the test matrices as a function of the standard commercial processing procedure, and the need for food/feed additive tolerances or section 701 MRLs.

(8) *Certification*. Certification of authenticity by the Study Director (including signature, typed name, title, affiliation, address, telephone number, date).

(9) *Tables/figures*. (i) Tables of raw data from the processing study, method recovery data, storage stability recovery data (if applicable); etc.

(ii) Graphs, figures, flowcharts, etc. (as relevant—include the processing procedure with weights of RAC and processed fractions).

(10) *Appendixes*. (i) Representative chromatograms, spectra, etc. (as applicable).

(ii) Reprints of methods and other studies (unless physically located elsewhere in the overall data submission, in which case cross-referencing will suffice) which will support the registrant's conclusions.

(iii) Other, comprising any relevant material not fitting in any of the other portions of this report.

(h) **References.** The following references should be consulted for additional background material on this test guideline.

(1) Environmental Protection Agency, Pesticide Reregistration Rejection Rate Analysis—Residue Chemistry; Follow-up Guidance for: Generating Storage Stability Data; Submission of Raw Data; Maximum Theoretical Concentration Factors; Flowchart Diagrams. EPA Report No. 737–R–93–001, February, 1993.

(2) Environmental Protection Agency, Pesticide Reregistration Rejection Rate Analysis – Residue Chemistry; Follow-up Guidance for: Updated Livestock Feeds Tables; Aspirated Grain Fractions (Grain Dust); A Tolerance Perspective; Calculating Livestock Dietary Exposure; Number and Location of Domestic Crop Field Trials. EPA Report No. 737–K–94–001, June, 1994.

(3) Environmental Protection Agency, Pesticide Reregistration Rejection Rate Analysis—Residue Chemistry; EPA Report No. 738–R–92–001, June, 1992.

(4) Environmental Protection Agency, FIFRA Accelerated Reregistration—Phase 3 Technical Guidance. EPA Report No. 540/09–90–078. (Available from National Technical Information Service, Springfield, VA).

(5) Environmental Protection Agency, Pesticide Registration Notice PR 86–5, Standard Format for Data Submitted under the FIFRA and Cer-

tain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), May 3, l986.