ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–30115; FRL–6028–2]

RIN 2070–AD23

Pesticides; Tolerance Processing Fees

AGENCY: Environmental Protection Agency (EPA).
ACTION: Proposed rule.

SUMMARY: The Food Quality Protection Act of 1996, by providing increased protection from the risks of pesticides especially to infants and children, has changed the number of regulatory actions that now fall under the heading of ''tolerance processing'' along with the responsibilities associated with reviewing tolerance petitions and other tolerance actions. In addition, over the last 15 years, factors such as expanded data requirements, changes in risk assessment methods, improvements in data base management and tracking systems, and the increasing complexity of scientific review of petitions have resulted in costs substantially exceeding the fees currently charged. Today, the difference between costs for processing tolerance actions and fees collected is substantial. This proposal, when promulgated, will make the tolerance processing system self-supporting. It would revise the fees charged for processing tolerance actions for pesticides under the Federal Food, Drug, and Cosmetic Act. The statute requires EPA to collect fees that will, in the aggregate, be sufficient to cover the costs of evaluating tolerances for pesticide products. Once in place, the financial burden to process tolerance actions would be borne primarily by those constituencies who directly benefit, rather than by the taxpayer.

DATES: Written comments, identified by the docket control number [OPP–30115], must be received on or before September 7, 1999.

ADDRESSES: Comments must be submitted by regular mail, electronically or in person. Please follow the detailed instructions for each method as provided in Unit I of the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Carol Peterson, Office of Pesticide Programs (7506C), U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone: (703) 305–6598; e-mail: peterson.carol@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Notice Apply to Me?

This proposed rule may directly affect any person who might petition the Agency for new tolerances, hold a pesticide registration with existing tolerances, or anyone who is interested in obtaining or retaining a tolerance in the absence of a registration. This group can include pesticide manufacturers or formulators, companies that manufacture inert ingredients, importers of food, grower groups, or any person who seeks a tolerance. Federal, State, local, territorial, or tribal government agencies that petition for, or hold, emergency exemption tolerances are exempt from this rule. The vast majority of potentially affected categories and entities may include, but are not limited to:

Category	NAICS	SIC	Examples of Potentially Affected Entities
Chemical Industry.	325320	0286	Pesticide chemical manufacturers, formulators
.....	115112	0287	Chemical manufacturers of inert ingredients

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. Other types of entities not listed above could also be regulated. If available, the four-digit Standard Industrial Classification (SIC) codes or the six-digit North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this notice applies to certain entities. To determine whether you or your business is regulated by this action, you should carefully examine the applicability provisions in the rule (see Unit V of this preamble). If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the ''FOR FURTHER INFORMATION CONTACT'' section.

B. How Can I Get Additional Information or Copies of this Document or Other Documents?

1. *Electronically*. You may obtain electronic copies of this document and various support documents from the EPA internet Home Page at http://www.epa.gov/. On the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register** - Environmental Documents.'' You can also go directly to the ''**Federal Register**'' listings at http://www.epa.gov/homepage/fedrgstr/.

2. *Fax on demand*. You may request to receive a faxed copy of this document, as well as some supporting information, if available, by using a faxphone to call (202) 401–0527 and selecting item 6037, the economic analysis and item 6038 ICR form 1915.01. You may also follow the automated menu.

3. *In person*. If you have any questions or need additional information about this action, you may contact the technical person identified in the ''FOR FURTHER INFORMATION CONTACT'' section. In addition, the official record for this notice, including the public version, has been established under docket control number OPP–30115 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of any electronic comments, which does not include any information claimed as CBI, is available for inspection in Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Public Information and Records Integrity Branch telephone number is 703–305–5805.

C. How and to Whom Do I Submit Comments

You may submit comments through the mail, in person, or electronically. Be sure to identify the appropriate docket number (i.e., ''OPP–30115'') in your correspondence.

1. *By mail*. Submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. *In person or by courier*. Deliver written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

3. *Electronically*. Submit your comments and/or data electronically by e-mail to: opp-docket@epamail.epa.gov. Do not submit any information electronically that you consider to be Confidential Business Information (CBI). Submit electronic comments as an ASCII file, avoiding the use of special characters and any form of encryption. Comment and data will also be accepted

on standard computer disks in WordPerfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number [OPP–30115]. Electronic comments on this notice may also be filed online at many Federal Depository Libraries.

D. *How Should I Handle CBI Information That I Want to Submit to the Agency?*

You may claim information that you submit in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult with the technical person identified in the ''FOR FURTHER INFORMATION CONTACT'' section.

E. What Should I Consider as I Prepare My Comments for EPA?

We invite you to provide your views on the various options we propose, new approaches we haven't considered, the potential impacts of the various options (including possible unintended consequences), and any data or information that you would like the Agency to consider during the development of the final action. You may find the following suggestions helpful for preparing your comments:

- Explain your views as clearly as possible.
- Describe any assumptions that you used.
- Provide solid technical information and/or data to support your views.
- If you estimate potential burden or costs, explain how you arrived at the estimate.
- Tell us what you support, as well as what you disagree with.
- Provide specific examples to illustrate your concerns.
- Offer alternative ways to improve the rule or collection activity.
- Make sure to submit your comments by the deadline in this notice.
- At the beginning of your comments (e.g., as part of the ''Subject'' heading), be sure to properly identify the document you are commenting on. You can do this by providing the docket number assigned to the notice, along with the name, date, and **Federal Register** citation.

II. Authority

Prior to being amended by the Food Quality Protection Act (FQPA), the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 321 *et seq.*) required EPA to collect fees to support the processing of petitions for tolerances (maximum allowable pesticide residue level) on raw agricultural commodities. FFDCA required EPA to collect such fees that will, in the aggregate, be sufficient to cover the costs of processing petitions, so that the tolerance program is as self-supporting as possible. FFDCA section 408(m)(1), as amended by FQPA, states that the Agency shall collect tolerance fees that, in the aggregate, will cover all costs associated with processing tolerance actions, including filing a tolerance petition and establishing, modifying, leaving in effect, or revoking a tolerance or tolerance exemption. These FQPA provisions also added to the types of regulatory actions that now fall under the heading of tolerance activities along with the responsibilities associated with reviewing tolerance petitions and other tolerance actions. EPA maintains the authority under section 408(m)(1)(D) to waive or refund part or all of the required fee when, in its judgement, the waiver or refund is equitable and not contrary to the purposes of the fee requirement.

III. Background

A. Regulatory History

Regulations governing the Agency's fee schedule were revised in 1972 and again in 1986 (40 CFR 180.33). In 1986, EPA used data from a 1983 Tolerance Cost Analysis to set tolerance petition fees ''based on the actual cost of providing services.'' The 1986 **Federal Register** Notice also stated fees were set at ''a level to recover through fees all costs of tolerance setting activity, less specifically waived or excluded activities.''

Cost data for each type of tolerance action were developed using employee time accounting information, along with data on the number of completed actions for tolerance petitions, the frequency of actions, and processing costs by fee categories. Fiscal year (FY) 1982 was the base year used to gather data for direct costs and completions by fee category. Using the figure of $38,900 as the average salary and expenses for a full-time EPA employee, per tolerance category, the total annual cost of the tolerance program (in FY82) per tolerance type was calculated.

Over the years, tolerance fees have been increased only to reflect annual increases in Federal salaries. For instance, in 1986, the fee for a petition to establish a new tolerance, or to increase the level of an established tolerance was set at $44,100, and the fee for a petition for an exemption from the requirement of a tolerance was set at $8,100. As a result of these annual incremental payroll increases, the 1998 fees for these actions are $65,600 and $12,100, respectively.

B. Revenues

In fiscal years 1986 through 1996, tolerance fee collections ranged from $1.1 to $2.5 million and averaged $1.8 million annually. During fiscal years 1994–1996, EPA waived and/or refunded fees that amounted to $329,000 annually: an average of $91,000 annually based on those found to be in the public interest or on economic hardship plus an average of $238,000 annually from petitions submitted by the U.S. Department of Agriculture's Interregional Research Project No. 4 (IR–4)[1].

In addition to tolerance fee revenues, other sources of revenue contribute in part to tolerance activities. Product maintenance fees are currently assessed on all registered products. These fees are used to support the reregistration program. Of the total $16 million collected annually, the Agency estimates that approximately $6.72 million in revenues goes to reassessing tolerances.

Registration fees were imposed in 1988 to cover most types of registration actions. Later that same year, FIFRA was amended and these fees were temporarily suspended. FQPA extended the suspension until September 2001. However, as part of the FY 2000 budget, the administration proposes to reinstate pesticide registration fees in FY 2000. An estimated 0.38 million to be collected from the registration fee will support analyses that are needed for both general registration program activities and for tolerance setting activities. Whether it occurs in FY 2000 or in FY 2002, the costs for these analyses are not included in this tolerance fee proposal.

IV. 1997 Cost Estimates

A. Factors

Since the 1983 cost analysis, factors such as expanded data requirements, changes in risk assessment methods, improvements in data base management and tracking systems, the increasing

[1]U.S. Department of Agriculture's Interregional Research Project No. 4 (IR–4) is a program that supports the registration of minor crop use pesticides by performing crop field trial studies and generating pesticide residue data.

complexity of scientific review, and the provisions of FQPA have resulted in costs substantially exceeding the revenues from current fees.

The new FFDCA section 408(m) states that EPA must collect fees sufficient in the aggregate over a reasonable term to cover the costs incurred in processing tolerance actions. However, under the new legislation, more tolerance actions and more types of tolerance actions are required. For example, because all tolerances now are set under section 408, EPA has the authority to collect monies to cover the costs incurred for processed food tolerances or tolerances for processed foods for residues that occur following the treatment of a raw agricultural commodity. In addition, because FQPA includes other ingredients in its definition of a pesticide chemical, other tolerances are subject to fees. Similarly, section 18 emergency exemptions now require tolerances and also are subject to fees.

In addition, FQPA increases the Agency's responsibilities associated with evaluating each tolerance petition. More analyses must be performed prior to the establishment of a tolerance. EPA must now consider aggregate risk, which includes drinking water and non-occupational exposure, common mechanism of toxicity, and other factors in its tolerance reviews. The Agency must also make a specific finding that the tolerances are protective with respect to infants and children. FQPA also requires that all existing tolerances (over 9,700) be reassessed within 10 years.

All of these factors--more tolerances required, more extensive and resource intensive evaluations, and comprehensive reassessments on a short time frame--mean that the difference between costs for processing tolerance actions and fees collected is substantial.

B. Cost Analysis

Using methods similar to those used in 1983, the Agency estimated the average cost of processing tolerance actions today. It found that from fiscal year prior to the enactment of FQPA, the unit cost (that is, the cost to process one new chemical tolerance petition) was $282,600. This cost rose to $376,900 per new chemical petition after FQPA. These figures show that FQPA mandates increased tolerance processing costs for a new chemical by 33 percent. In the first 21 months since FQPA, the Agency's total costs for processing petitioned tolerances was estimated to be $7.7 million annually.

FQPA's mandate that EPA reassess all existing tolerances within a 10–year period also adds a substantial cost to the program--approximately $20.1 million annually. Many tolerances are currently being reassessed as part of the Agency's reregistration efforts on all pesticide chemicals registered prior to 1984. For these chemicals, the Agency estimates that additional analyses required by FQPA will cost about $1.7 million annually for those chemicals for which a reregistration eligibility decision has been made, and about $10.2 million annually for those pre-1984 chemicals for which a risk assessment has not yet been completed. Some examples of new program costs for which fees may be charged include the reassessment of tolerances established after 1984 and all tolerances on other chemicals. Annual costs for these two categories will amount to about $2.0 million and $4.7 million, respectively.

The overall total for processing tolerance actions for registration and reassessment activities is estimated to be $27.8 million annually. Since $7.10 million will be collected through other fees, the total annual additional amount that the Agency needs to recoup for all tolerance activities is $20.7 million. Copies of the Agency's ''Tolerance Fee Economic Analysis'' and supplementary materials are available in the public docket at the address given above in ADDRESSES.

C. Future Costs

EPA anticipates additional costs for processing tolerance actions in the near future. The costs will be incurred upon the implementation of FFDCA section 408(b)(2)(E) ''Data and Information Regarding Anticipated and Actual Residue Levels,'' section 408(b)(2)(F) ''Percent of Food Actually Treated,'' and section 408(f) ''Special Data Requirements.'' Under these sections, whenever the Agency uses or has used anticipated or actual residue levels from field monitoring, in the evaluation of a new or existing tolerance, it must call-in additional data within 5 years to ensure that the residue levels (and associated risks) of those of the crops have not increased unacceptably. EPA is in the process of developing workplans and estimating resource needs for implementing these sections of the law in the hope of finalizing a policy by the end of 1999. Rather than delay today's proposal, the Agency hopes to issue an amendment to the Final Rule on Tolerance Fees sometime in the later part of the year 2000 to include these costs in the fee schedules.

Additional costs relating to tolerances also will stem from analyses such as, special subpopulations susceptibilities, common mechanisms of toxicity from similar substances, and endocrine effects (FFDCA sections 408(b)(2)(C) ''Exposure of Infants and Children'' and 408(p) ''Estrogenic Substances Screening Program''). The current state of scientific knowledge does not lend itself to the development and implementation of standardized guidelines in these areas. Determining and quantifying appropriate endpoints and incorporating these endpoints into risk assessments is still very much under debate. EPA is currently working with the scientific community to determine the proper course of action and establish appropriate protocols. Once policies are made in these areas and guidelines are established, the resources required to review the data and perform the analyses will be estimated and the tolerance fee schedule will be amended to include the additional costs.

V. New Tolerance Fee System

The goal of designing and updating a new tolerance fee system is to develop a truly self-supporting tolerance program, as required by Congress. The criteria that were used in considering various approaches was a system that would be reasonable, uncomplicated, fair and equitable. Moreover, the new fee system must be fully accountable. EPA is committed to subject whatever approach is finally adopted to an annual independent audit. This will ensure the resulting tolerance fee system is adequately covering our needs and, at the same time, not overcharging those required to pay.

A. Possible Approaches

Once the total costs of the tolerance programs were determined, the question that remained was how to devise a system to recoup the money--not only who should pay, but what basis should be used to determine the fee amounts. Various approaches were considered. Each was based on a specific parameter, or factor, that would promote the Agency's goal of reducing the risks associated with pesticides.

For example, tolerance fees could be based on a sliding scale. Differential fees could be risk-based or set according to the toxicity of a chemical. The more toxic a chemical, the higher the tolerance fee would be. Biopesticides in general, reduced-risk chemicals, or candidates for FIFRA 25(b) exempted chemicals would pay the lowest fees. Another approach discussed was setting tolerance fees based on chemical use and/or usage. Similar to this approach is a fee based on sales. The underlying concept in these examples is that the more widely used chemicals usually generate the most sales for a company,

thus putting it in a better position to absorb an increased fee. Products with niche markets, or those used on minor uses would incur a much lower fee.

B. Proposed Approach

While the above approaches, and many others considered, have merit, they were dismissed for not meeting one or more of the accepted criteria. In many cases, some sort of evaluation had to be performed in order to determine the appropriate fee. Chemicals could not be easily classified until the end of our review and additional fees would have to be collected or fees rebated. Some fee structures considered were too costly to administer, required intricate screening procedures or complicated tracking systems, or were beyond our legislative authority.

The Agency opted to propose tolerance fees based on the resource needs required to review a specific type of tolerance action. Even within this approach, there were several different ways to identify the tolerance categories and assess the appropriate fee amounts. The Agency considered: (1) Continuing the practice of charging by petition, (2) charge by crop, use, or chemical, or (3) charge by tolerance. Each of the first two had significant problems. Moreover, since the Agency is shifting toward a more systematic and consistent way of tracking its actions by tolerance, it sought to design the new tolerance fee system on a per tolerance basis. The following is a detailed description of its preferred approach for a new tolerance fee system.

1. *Petitioned tolerance actions*. The Agency proposes to set new tolerance fees based on resource needs for each type of tolerance action. This means that the Agency would charge a significantly larger amount for the first tolerance of a chemical, whether it be a new or registered chemical, since this would require the most work to process. Subsequent tolerances for the same crop or tolerances for additional crops within the same petition would be charged considerably less. In contrast, a separate new food use tolerance petition submitted at a later date, would be charged a slightly higher fee per tolerance than if the use was included in the original petition because processing it would require some amount of rework. This means that, resources are used to review the existing file and apply the new information to the previous assessments. A single tolerance fee was set for this category because historically, petitioners have submitted one crop per new use petition. If this practice is likely to change, (for example a petitioner would choose to add several crops to its label), the Agency could consider an incremental fee structure similar to a first food use petition. Tolerances for antimicrobial pesticides would be charged a different fee because these types of pesticides require a different set of data that must be submitted. Fees for temporary tolerances for experimental use permits, and tolerance exemptions also reflect the reduced data sets, and thus reduced review resources, that are required.

Fees will be imposed for any crop and/or use that ultimately results in the establishment of a tolerance or exemption from the requirement of a tolerance. This includes direct application to an agricultural plant or crop, preplant uses in the soil, or indirect uses that may result in inadvertent residues in a raw agricultural commodity. Some examples of when a tolerance fee would be imposed, in addition to direct agricultural crop uses, are for pesticide residues that indirectly occur in food or feed as a result of aquatic weed control in irrigation ditches, mosquito control use, bulk storage fumigation use, as a bird repellent, or for residues that could occur in rotated crops. Dermal applications to livestock, use in ponds or reservoirs for weed control or disease control of fish, shellfish, oysters etc., forestry uses (for residues in maple sap), and use in or around apiaries (residues in honey or beeswax) are all subject to tolerance fees. Similarly, uses of pesticides in food or feed handling establishments, such as restaurants, breweries, supermarkets, processing plants, dairies, or canneries, are subject to tolerance fees should residues occur.

For the purposes of assessing a fee, an import tolerance (a pesticide tolerance with no current U.S. uses or registrations) would be treated as if there was a U.S. registration for the chemical. The party wishing to obtain or retain a tolerance for import purposes would be responsible for the payment of the fee. Further, under this revised fee system, the tolerance modification category includes renewals, extensions, and conversions of a temporary tolerance or time-limited (non-section 18) tolerance as well as all amendments to existing tolerances.

i. *Counting tolerances*. The new fee would be based on the number of individual tolerances required rather than on a petition basis. (Currently, one petition may include up to nine crops for one base fee.) This means that every food or feed item for which a tolerance is either established or exempted, that is, every line item listed in Title 40 of the Code of Federal Regulations (CFR) is counted as one tolerance. A crop group tolerance (a single tolerance which is applicable to a group of similar crops) would be considered one tolerance action. An exemption from the requirement of a tolerance for ''all food commodities'' would be considered one tolerance action, whereas a tolerance exemption request for a chemical on barley and corn would be considered two tolerance actions.

A separate fee would be imposed for each raw and processed commodity that would require a tolerance or exemption. If residues are found to concentrate in processed commodities or are found in livestock tissue, separate tolerances would be required. A chemical used on almonds therefore would be charged for a minimum of two tolerances--on the raw commodities nutmeats and hulls, whereas a chemical used on oranges would require one tolerance for the fruit (the raw commodity), and if residues were found to concentrate in the dry pulp, peel, oil, molasses, or juice, additional tolerances would be needed and fees charged. In addition, if the almond hulls or the orange pulp or molasses were to be used as feed and livestock feeding studies are required, then a fee for each tolerance required on meat, fat, meat by products, milk, poultry and eggs would be charged.

An example of how this scheme would work is if a company wished to register a new active ingredient on cotton. The company would petition the Agency for tolerances on the raw commodities cottonseed and forage (two tolerances). Processing studies reveal that the chemical concentrates in the meal, crude oil, and refined oil (three tolerances) and livestock feeding studies show that hulls fed to cattle result in residues in the meat, fat and milk (three tolerances). Using the table in Unit V.B.1.iii. of this preamble, the registrant would be charged a total of $537,300 in tolerance fees ($504,400 for the first tolerance of a new active ingredient, plus $4,700 for each of the seven additional tolerances). If however, in a subsequent petition, this company wished to add cotton to an existing food-use product label, it would be charged $135,200 ($16,900 for each of the eight new use tolerances) because the review costs are substantially less than for a new active ingredient.

ii. *Deficient petitions*. The Agency would not process a petition that is deficient. Administrative deficiencies that may be easily corrected, such as improper formatting, illegible pages, *etc.*, would not incur any penalty if the error can be corrected within 14 calendar days. If the petitioner believes that the correction cannot be made

within this time frame, it must notify the Agency. If, after 14 days the petitioner has not responded, the petition would be treated as if it has been withdrawn and the original fee, less $7,500 for handling and initial review, would be returned.

Once the Agency has initiated its scientific review, a resubmission fee would be imposed for substantially flawed petitions that require one or more resubmissions of data or other required information. Defective studies cost the Agency a tremendous amount of resources and delay the review of the petition considerably. Resources are wasted reviewing an unacceptable study and, in many cases, more times and effort is spent working with the affected petitioner to generate useful data. For this reason, EPA is instituting an admittedly large penalty for ineffective and/or poorly conducted studies. We hope that this will serve as an incentive to submit only quality data and information for review.

Petitioners would have up to 75 calendar days from the date of EPA notification to correct the deficiency without penalty, after which an additional 35 percent of the original fee would be charged. The resubmission fee would be required at the time the requested studies and/or other material are submitted. If the correction cannot be made within this time frame, the petitioner must notify the Agency, as soon as possible within the 75 days, of the circumstances surrounding the delay. If, after 75 days the petitioner has not responded, or subsequently fails to submit the required material within the negotiated time frame, the petition would be treated as if it had been withdrawn in the manner consistent with 40 CFR 152.105, and the original fee would not be returned. A deficiency that would warrant the resubmission fee would include a study that is not fully acceptable and must be repeated in its entirety or in parts (*e.g.*, a toxicology study that is categorized as ''non-upgradable''), or any other significant issue that prevents the continuation of the science review or the Agency from reaching a regulatory decision.

iii. *Fee schedule.* Using this scheme, EPA proposes the following fee schedule for petitioned tolerance actions.

Petitioned action	Fee
First Food-use Petition for a New Active Ingredient[1]	(1st tol.) = $504,400 (add'l tol.) = 4,700
First Food-use Petition for a Registered Non-Food Active Ingredient[1]	(1st tol.) = 468,800 (add'l tol.) = 4,700
New Use Tolerance or Exemption for an Active or Other Ingredient	16,900
Temporary Tolerance or Exemption for an Experimental Use Permit	51,200
Time-limited Tolerance for an Emergency Exemption	0
Exemption from the Requirement of a Tolerance for an Active Ingredient[1]	145,400
Tolerance Modification for an Active or Other Ingredient	4,400
Tolerance for an Other Ingredient	62,300
Exemption from the Requirement of a Tolerance for an Other Ingredient	59,300
Tolerance or Exemption for an Antimicrobial Active Ingredient	68,200
Request for Fee Waiver or Refund[2]	7,500

[1] Excluding antimicrobial active ingredients.
[2] Fee will be returned if waiver or refund is warranted.

2. *Reassessed tolerances.* As with petitioned tolerances, EPA proposes to set fees for reassessing tolerances based on estimated resource needs for each type of reassessment. Different fee amounts would be charged for a pre-1984 chemical for which a Reregistration Eligibility Decision document (RED) has been completed, a pre-1984 chemical that is currently in the reregistration queue, or a chemical for which tolerances were set after 1984. Differences would take into account the amount of review that has already taken place (*i.e.*, whether the chemical has or will go through, or is even subject to, the reregistration process), and the additional analyses that must be performed due to FQPA provisions.

For tolerances that were reassessed as part of a reregistration eligibility decision that has already been made, the basic science evaluation has already occurred. For these chemicals, the Agency must go back and perform the FQPA analyses, such as a drinking water exposure assessment, the aggregate risk assessment, and the special finding for infants and children. The Agency, however, must perform a complete risk assessment, including the FQPA requirements, for chemicals that had not gone through reregistration at the time FQPA was passed, or are not subject to reregistration, i.e., those chemicals registered between November 1984 and August 1996. The fee proposed for the chemicals subject to reregistration but for which a RED is issued after the enactment of FQPA does not reflect the actual amount of resources needed to review these tolerances because credit is given for product maintenance fees that have already been paid. Moreover, for the tolerances of chemicals that were registered after November 1984 and as such are not subject to reregistration, the Agency must reevaluate all existing data and perform a complete risk assessment.

i. *Counting tolerances.* For the group of chemicals that are already registered, tolerances have been added over the lifetime of the registration (some older chemicals have over 100 tolerances). The amount a registrant would pay for tolerance reassessment would depend on the total number of tolerances to be reassessed. The Agency would charge one amount for the first tolerance and a lesser amount for additional tolerances. As with petitioned tolerance actions, a crop group tolerance would be considered one tolerance action. Similarly, an exemption from the requirement of a tolerance for ''all food commodities'' would be considered one tolerance action. A chemical with tolerances on corn (fresh, grain, and forage) would be considered three tolerance actions. A tolerance exemption for a chemical on barley and corn would be considered two tolerance actions.

ii. *Fee schedule.* Using this scheme, the Agency proposes the following fee schedule for tolerance reassessments.

Tolerance reassessment	Fee
Tolerance for an Active Ingredient for which a Reregistration Eligibility Document was issued before August 1996	$12,500

Tolerance reassessment	Fee
Tolerance for an Active Ingredient for which a Reregistration Eligibility Document is issued after August 1996[1]	(1st tol) = 227,700 (add'l tol) = 500
Tolerance for an Active Ingredient First Registered between November 1984 and August 1996	(1st tol) = 289,800 (add'l tol) = 1,700
Active Ingredient Tolerance Exemption	20,600
Other Ingredient Tolerance	201,400
Other Ingredient Tolerance Exemption	79,300
Request for Fee Waiver or Refund[2]	7,500

[1] The calculated tolerance fees for the chemicals in reregistration are offset by monies received via product maintenance fees.
[2] Fee will be returned if waiver or refund is warranted.

iii. *Payment schedule.* Fees generally would be collected prior to the commencement of the reassessment and would be independent of the resulting tolerance decision. Itemized payment statements would be sent to the registrant(s) of a technical active ingredient (or chemical case) at the beginning of the fiscal year that the tolerance reassessment is scheduled. The registrant(s) would have 90 days to remit the appropriate amount. Registrants who share the responsibility for a single active ingredient or chemical case will be encouraged to work together to determine how the fee will be paid. The Agency will include in its reassessment only those tolerances for which it receives payment. For those chemicals whose tolerance reassessments have commenced prior to the promulgation of this rule, a bill will be sent to affected parties for work performed. A tolerance reassessment will not become final until the required fee is submitted. EPA will revoke any existing tolerance for non-payment of the fee.

3. *Tolerance fee waivers.* As part of the new fee structure, the Agency proposes to grant routine fee waivers for certain tolerance actions. Fee waivers are proposed for:

i. *Petitions submitted by IR–4.* U.S. Department of Agriculture's Interregional Research Project No. 4 (IR–4) is a program that supports the registration of minor crop use pesticides by performing crop field trial studies and generating pesticide residue data. Since this program is supported by taxpayer dollars, charging a fee would be contrary to the purposes of this proposal.

ii. *Minor use tolerances actions, except when the minor use constitutes the first food use or the sole use(s) of an existing chemical.* Traditionally, minor use pesticides are produced for niche markets with often low profit margins. Because of this, many minor use crop farmers do not have a wide selection of pest control products and an increase in fees may jeopardize the continued registrations. FQPA has essentially put into law the Agency's long standing policies to aid the registration and retention of pesticides used on minor crops. Granting an automatic fee waiver for tolerance actions for minor use crops is consistent with Agency policy and Congressional intent. For the purposes of this proposal, EPA is defining a minor use as any crop use other than that on alfalfa, almonds, apples, barley, beans (dry and snap), canola, corn (field, sweet, and pop), cottonseed, grapes, hay, pecans, potatoes, rice, rye, sorghum, soybeans, sugarbeets, sugarcane, sunflower, oats, oranges, peanuts, tomatoes, or wheat.

Fees for pesticide chemicals used solely on minor uses, however, cannot be automatically exempt from the proposed fees because of the large amount of resources required to process or reassess the tolerances. While the submission of a new chemical registration for strictly minor uses is extremely rare, there are a handful of existing pesticide chemicals that are registered for use only on minor crops. To establish or reassess the tolerances the Agency must still review a full set of data and conduct a complete risk evaluation. For all minor use only chemicals, the Agency proposes to impose a fee equivalent to a single, first tolerance, temporary tolerance or tolerance exemption. For example, if a registrant is applying for a new chemical registration and has submitted a tolerance petition for use on garden beets, onions, and turnips, the fee would be $504,400, regardless of how many individual tolerances were established. Similarly, if an existing chemical was registered in 1985 for use on garden beets, onions, and turnips and tolerances were established for beet roots, beet greens, onion bulbs, turnip roots, turnip tops, and several livestock commodities, the registrant would be charged a tolerance reassessment fee of $289,800.

iii. *Time-limited tolerances for emergency exemptions.* If, in a single year, there occurs a severe pest infestation for which there is no registered pesticide available, EPA may grant an emergency exemption from FIFRA requirements for that pesticide. And because an emergency situation is occurring, the Agency must respond quickly. The passage of FQPA now requires the Agency to set time limited tolerances for these emergency uses. The States submit the exemption requests and accompanying tolerance petitions on behalf of their growers. Due to the urgent nature of these types of tolerance actions, and given that the state governments would be paying the fees with taxpayer dollars, charging a fee would be contrary to the purposes of this proposal.

iv. *Petitions to revoke a tolerance and tolerance revocations.* Imposing a fee for these types of tolerance actions would be impractical.

v. *Biopesticide tolerance actions, except plant-pesticides.* Biopesticides usually affect a single pest and, similar to minor use pesticides, often have low profit margins. Because these pesticides are by and large less risky than conventional, synthetic pesticide chemicals, EPA has adopted a number of policies to encourage their development and registration. The assessment of biopesticides requires a different and abbreviated set of data for registration and any associated tolerance actions, therefore less resources are generally required to reach a regulatory decision. Waiving the tolerance fee is consistent with existing policies. The tolerance review for plant-pesticides, however, cannot be waived at this time. Although the Agency also believes that plant-pesticides are inherently lower risk, the fees cannot be routinely waived because of the large amount of resources are necessary to process or reassess the tolerances. Moreover, these products often become profitable soon after introduction.

vi. *Other ingredients generally regarded as safe (List 4A inerts).* Tolerance reassessment fees would not be required for other ingredients the Agency has declared as minimal risk and generally regarded as safe, that is, those currently on List 4A. Fees for petitioned tolerance exemptions for

other ingredients to be added to List 4A would be refunded once it was determined that the List 4A designation was warranted. The most current listing of the List 4A inerts can be found posted on the Internet on EPA's home page at http://www.epa.gov/opprd001/inerts/lists.html, or by writing Registration Support Branch (Inerts), Registration Division (Mail Code 7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

vii. *Tolerance exemptions for chemicals exempted from FIFRA regulations under section 25(b).* Similarly, tolerance reassessment fees would not be required for active ingredients that have been exempted from FIFRA regulation under section 25(b). These chemicals have been declared by the Agency to be of a character which is unnecessary to be subject to the Act in order to carry out its purposes. Fees for petitioned tolerance exemptions for active ingredients to be added to this list would be refunded once it was determined that the 25(b) designation was warranted. The list of FIFRA exempted substances can be found in 40 CFR part 152.25.

EPA believes that the above waivers are equitable and not contrary to the purposes of the fee requirement, yet invites the public to comment on this issue. Other views have been raised. For example, although it is the Agency's policy to promote the development and use of biopesticides, some companies engaged in the registration of these types of pesticides are large and can afford to pay a fee. The Agency recognizes that there are other ways to champion these products without granting a full fee waiver. One way is to grant fee waivers via the submission of a small business waiver request (see below). Similarly the minor use fee waiver would also apply to many biological pesticide petitions. Another option is to set fees for biologicals based on the percentage of the fee imposed for a conventional chemical. In deliberations for this fee proposal, the Agency found administrative costs and complexity argued against a case-by-case analysis for these categories. However, EPA would like to hear differing views.

The Agency estimates that revenues waived from these waived actions will be $2.5 million annually for petitioned tolerance actions and $2.4 million annually for tolerance reassessments. Because EPA must collect fees ''in the aggregate'' to cover its costs, all of the calculated fees for each category must be adjusted upwards in order to recover the $4.9 million annual revenue shortfall. Accordingly, the Agency raised the fees by 48 percent for the petitioned tolerance categories and 23 percent for reassessed tolerance categories.

EPA also will continue the practice of granting fee waivers on a case-by-case basis when warranted, and when requested in writing by the petitioner or registrant. For these requests, OPP has revised and expanded the current criteria for granting fee waivers for safer products, products that are in the public interest, and to those registrants who demonstrate an economic hardship. An updated Pesticide Registration Notice will be made available in draft form for public comment. A fee of $7,500 shall accompany every waiver or refund request. The fee will be returned if the request is granted. Conversely, the fee will be forfeited if the request is denied.

4. *Implementation*. Petitioners would continue following the established procedures outlined in the current regulations. When applying for a tolerance or tolerance exemption, petitioners would send EPA their remittance, data, and supporting materials. The cover letter, application or petition, data, and all supporting materials would continue to be sent to EPA's Office of Pesticide Programs in Washington, DC. The payments themselves would continue to be sent to EPA's Financial Management Division (FMD) in Pittsburgh, Pennsylvania. The Agency would not begin processing the petition until it had been notified by FMD that the check had cleared.

For tolerances that are to be reassessed, the Agency would send affected registrants a bill at the beginning of each fiscal year for those chemicals that are scheduled to be reevaluated during that year. Registrants would be sent a pre-printed form listing their chemical and all the associated tolerances. On the form, they would be asked to verify the list, identify those tolerances they wish to support, and calculate the appropriate fee amount. The Agency will use the information on the response forms and include only those tolerances for which the fee has been paid in its risk assessment. Multiple registrants of the same active ingredient would be given 90 days to coordinate their response and jointly pay the required fee for that chemical. If no registrant comes forth to pay for a particular tolerance, the Agency will publish a notice in the **Federal Register** which will alert other potential impacted parties and provide them with the opportunity to support the reassessment of that tolerance. Tolerances will be revoked for non-payment of fees.

i. *Annual adjustments*. EPA proposes to continue the practice of raising fees annually to reflect inflation. Currently these annual fee adjustments are based on the total percentage change in basic pay in Federal employee salaries, that is, the Cost of Living Adjustment, or COLA. The Agency has looked at the issue of adjusting fees over time and proposes to continue to link the increases to the COLA. Other approaches that were suggested were tying the annual adjustment to the total percentage change that occurred during the previous year in the Consumer Price Index (CPI), or perhaps base the adjustment on the greater of either the COLA or the CPI. EPA invites comment on this issue. In addition to annual adjustments to the fee scale, the Agency intends to evaluate the tolerance fee system periodically to determine if revenues are adequately covering costs and whether fees should be adjusted accordingly.

ii. *Transition*. For the purposes of FFDCA section 408(m), a tolerance or exemption will not be considered officially granted or reassessed until the appropriate fee is paid. Registrants of chemicals for which a tolerance action has begun and not yet granted or declared reassessed prior to the finalization of this rule would be required to pay the revised fee. Petitioners or registrants that are in the tolerance review queue upon publication of this proposal would be subject to retroactive billing.

Because this document is a proposal, it is important to note that the individual fee amounts proposed may change upon promulgation due to the comments received. Affected parties must keep in mind that, since the Agency must collect fees to cover its costs ''in the aggregate,'' a decrease in one fee will result in the increase of another.

VI. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) determined that this proposed rule is not a ''significant regulatory action.'' The Agency determined that this rule, when promulgated, is estimated to impose an aggregate regulatory burden of $20.7 million annually and therefore is unlikely to have a major economic impact on pesticide registrants. Promulgation of

this proposed rule will have no impact on any other sector of the economy, or on any other government entities, programs or policies. In addition, the proposed rule is consistent with the purposes of FFDCA, and does not conflict with any other statutory mandate or with the principles of the Executive Order.

B. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Agency hereby certifies that this action will not have a significant economic impact on a substantial number of small entities. This determination is based on the Agency's 1997 Cost Analysis which is available in the OPP public docket for this rulemaking. In addition, for those small businesses that are affected by this action, EPA has provided the opportunity to request fee waivers and has set forth criteria based on economic hardship. Tolerance fee waivers will be granted on a case-by-case basis for petitioners or registrants who cannot pay.

For this analysis, we have adopted the definition of small businesses from FIFRA section 4(i)(5)(E)(ii)(I): Entities with 150 or fewer employees and an average annual gross revenue of $40 million over a 3–year period. This definition differs from the standard definition applied under the Regulatory Flexibility Act (RFA). According to section 601(3) of the RFA, agencies must use the definition of ''small business'' that is provided under the Small Business Act, 15 U.S.C. section 631 *et seq.*, unless it establishes an alternative definition. The agency may use the alternative definition for RFA purposes only after it has consulted with the Office of Advocacy of the Small Business Administration (SBA) and provided an opportunity for public comment.

According to SBA, small entities vary by Standard Identification Code (SIC), and, for chemical manufacturers, are based solely on the number of employees. Most establishments producing organic chemicals are defined as small if they have fewer than 500 employees. For chemical manufacturing, however, the number of employees may not be closely related to the total annual sales of a company. Since chemical testing primarily requires a financial outlay, EPA believes that the number of employees is a less reliable measure of a company's ability to pay applicable fees than is a company's total annual sales. Therefore, in this proposed rulemaking, the Agency is proposing to use the FIFRA definition of ''small business'' for RFA purposes. This definition is discussed in the document that gives additional information on small entity impacts.

EPA is hereby seeking comment on the use of the Agency's definition of ''small business,'' as well as on the ''Small Entity Impacts of the Economic Analysis of Proposed Tolerance Fee Schedule'' document. EPA is also consulting with the Office of Advocacy of the SBA concerning the Agency's use of the EPA definition. Any comments regarding the impacts that this action may impose on small entities should be submitted to the Agency in the manner specified in Unit I of this preamble.

C. Unfunded Mandates Reform Act

Under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub.L. 104–4), EPA has determined that this action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. The cost associated with this action are described in the Executive Order 12866 section above. Therefore, this action is not subject to the requirements of sections 202 and 205 of the UMRA.

D. Consultation and Coordination with Indian Tribal Governments

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. Today's proposal would implement requirements specifically set forth by the Congress in FFDCA without the exercise of any discretion by EPA. The proposal does not significantly or uniquely affect the communities of Indian tribal governments. Tribal governments would not be subject to the requirements of today's proposal. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this proposal.

E. Enhancing Intergovernmental Partnerships

Under Executive Order 12875, entitled *Enhancing Intergovernmental Partnerships* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. Today's proposal would implement requirements specifically set forth by the Congress in FFDCA without the exercise of any discretion by EPA. It would not create a mandate on State, local or tribal governments. The proposal would not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this proposal.

F. Children's Health Protection

This proposed rule is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866 (see Unit VI.A. above). In addition, this proposed rule is procedural in nature and does not involve decisions on environmental health risks or safety risks that may disproportionately affect children.

G. National Technology Transfer and Advancement Act

This proposed regulation does not involve technical standards. As such, the requirement in section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), (15 U.S.C. 272 note) which directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or impractical, does not apply to this action. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. EPA invites public comment on this conclusion.

H. Environmental Justice

This proposed rule does not directly affect minority populations or low-income groups. Therefore, under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency does not need to consider environmental justice-related issues regarding the environmental and health conditions in low-income and minority communities.

I. Paperwork Reduction Act

The new information collection requirements contained in this proposed

rule have been submitted to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq, and in accordance with the procedures at 5 CFR 1320.11. An Information Collection Request (ICR) document has been prepared by EPA (EPA ICR No. 1915.01) and a copy may be obtained from Sandy Farmer, OP Regulatory Information Division; U.S. Environmental Protection Agency (2137); 401 M St., S.W.; Washington, DC 20460, by calling (202) 260–2740, or electronically by sending an e-mail message to ''farmer.sandy@epa.gov.'' An electronic copy has also been posted with the **Federal Register** notice on EPA's homepage with other information related to this action.

The information collection requirements related to the tolerance petition process are already approved under OMB control number 2070–0024 (EPA ICR #597), and this proposed rule does not affect that activity. However, this proposed rule does contain two minor information collection activities that are not currently approved, including the requirements related to the identification of the tolerances that the Agency should include in the reassessment of the chemical, and the process for requesting a fee waiver or refund. These new activities are discussed in the ICR document, and are not effective until EPA issues a final rule and until OMB has approved the information collection under the Paperwork Reduction Act (PRA) and assigned an OMB control number to that approval. An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information subject to OMB approval under the PRA unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after initial publication in the **Federal Register**, are maintained in a list at 40 CFR part 9.

The annual burden for the proposed information collection activities contained in this proposed rule are estimated to be 2.3 hours for each submission of the tolerance reassessment form, 2 hours for each fee waiver or refund request submitted, and 0.3 hours to maintain records. These estimates include the time needed to become familiar with the requirements (first year implementation is an additional 1 hour per registrant), review the instruction, complete the form, and transmit or otherwise disclose the information. Under the PRA, ''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. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information

Any comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, increasing electronic submissions, etc. may be sent to EPA at the address provided in Unit I of this preamble. Please include the docket number and ICR number in any correspondence related to the information collection components of this proposed rule. The final rule will respond to any comments received on the information collection requirements contained in this proposal.

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements

Dated: May 28, 1999.

Carol M. Browner,

Administrator.

Therefore, 40 CFR part 180 is proposed to be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 would continue to read as follows:

Authority: 21 U.S.C. 321(q), 346a, 371.

2. Section 180.33 would be revised to read as follows:

§ 180.33 Fees.

(a) *Fees for petitioned tolerance actions.* (1) Each petition to establish, modify, or leave in effect a tolerance or exemption from the requirement of a tolerance must be accompanied by the appropriate fee as listed in the following table unless such fee is waived according to paragraph (e) of this section.

Petitioned action	Fee
First Food-use Petition for a New Active Ingredient[1]	(1st tol.) = $504,400 (add'l tol.) = 4,700
First Food-use Petition for a Registered Non-Food Active Ingredient[1]	(1st tol.) = 468,800 (add'l tol.) = 4,700
New Use Tolerance or Exemption for an Active or Other Ingredient	16,900
Temporary Tolerance or Exemption for an Experimental Use Permit	51,200
Time-limited Tolerance for an Emergency Exemption	0
Exemption from the Requirement of a Tolerance for an Active Ingredient[1]	145,400
Tolerance Modification for an Active or Other Ingredient	4,400
Tolerance for an Other Ingredient	62,300
Exemption from the Requirement of a Tolerance for an Other Ingredient	59,300
Tolerance or Exemption for an Antimicrobial Active Ingredient	68,200
Request for Fee Waiver or Refund [2]	7,500

[1] Excluding antimicrobial active ingredients.
[2] Fee will be returned if waiver or refund is warranted.

(2) A petitioner must remit a fee for each tolerance requested for a pesticide chemical residue. A tolerance fee is required for each food or feed item that requires a tolerance or exemption from the requirement of a tolerance. Similarly, a tolerance fee is required for each processed food or feed item and each livestock food or feed item that requires a tolerance be established. A tolerance fee is required for residues that occur in or on individual food or feed items as a result of indirect pesticide use.

(3)(i) A crop group tolerance petition, for the purposes of assessing a tolerance fee under this paragraph, will be

considered a request for a single tolerance action.

(ii) A request for an exemption from the requirement of a tolerance on all food commodities, for the purposes of assessing a tolerance fee under this paragraph, will be considered a request for a single tolerance action.

(iii) A modification to a tolerance includes renewals, conversions of a temporary tolerance or time-limited tolerance as well as all amendments to existing permanent or temporary tolerances or tolerance exemptions.

(iv) For new chemical or first food-use tolerance petitions submitted for minor uses only, a fee equivalent to a single, first tolerance, temporary tolerance or tolerance exemption is required.

(4) A petition will not be accepted for processing and the Agency will take no regulatory action until the required fee is submitted.

(5) For the purposes of section 408(m) of the Federal Food, Drug, and Cosmetic Act, a tolerance or tolerance exemption will not be granted until the appropriate fee has been received.

(b) *Fees for reassessed tolerances.* (1)(i) Applicable fees are required for each Agency action to modify or leave in effect an existing tolerance or exemption from the requirement of a tolerance that results from an Agency-initiated tolerance reassessment activity. The fee listed in the following table must be paid prior to the reassessment of the established tolerances of a particular chemical upon notice from the Agency. Such notice shall be sent to each producer of the particular pesticide chemical.

Tolerance reassessment type	Fee
Tolerance for an Active Ingredient for which a Reregistration Eligibility Document was issued before August 1996	$12,500
Tolerance for an Active Ingredient for which a Reregistration Eligibility Document is issued after August 1996[1]	(1st tol) = 227,700 (add'l tol) = 500
Tolerance for an Active Ingredient First Registered between November 1984 and August 1996	(1st tol) = 289,800 (add'l tol) = 1,700
Active Ingredient Tolerance Exemption	20,600
Other Ingredient Tolerance	201,400
Other Ingredient Tolerance Exemption	79,300
Request for Fee Waiver or Refund [2]	7,500

[1] The calculated fee is offset by monies received via product maintenance fees.
[2] Fee will be returned if waiver or refund is warranted.

(ii) Where a chemical has no registered uses in the United States, or where no registrant pays the applicable fee to support a particular tolerance to be reassessed for a chemical, a notice shall be published in the **Federal Register** to provide other potentially impacted parties the opportunity to support the retention of that tolerance by petitioning the Agency.

(2) A single tolerance fee is required for every tolerance established or exemption from the requirement of a tolerance per raw agricultural commodity. Similarly a single tolerance fee is required for each processed commodity and each livestock commodity with an established tolerance. A tolerance fee is required for residues that occur in or on individual food or feed items as a result of indirect pesticide use.

(3)(i) An established crop group tolerance, or an existing exemption from the requirement of a tolerance on all food commodities, for the purposes of assessing a tolerance reassessment fee under this paragraph, will be considered a single tolerance action.

(ii) An existing exemption from the requirement of a tolerance on all food commodities, for the purposes of assessing a tolerance reassessment fee under this paragraph, will be considered a single tolerance action.

(4) For the purposes of section 408(m) of the Federal Food, Drug, and Cosmetic Act, a tolerance reassessment will not become final until the required fee is submitted.

(5) The Administrator shall revoke a tolerance or exemption from the requirement of a tolerance for non-payment of the applicable fee.

(c) *Withdrawal of a petition.* If a petition is withdrawn by the petitioner before significant Agency scientific review has begun, the fee, less $7,500 for handling and initial review, shall be returned. No fee will be returned after the commencement of scientific review. If a withdrawn petition is resubmitted, it must be accompanied by the fee required in paragraph (a) of this section for a new submission.

(d) *Deficient petitions.* (1) If a petition is not accepted for processing because it is administratively incomplete, and the petitioner rectifies the problem within 14 calendar days, no resubmission fee will be imposed. If the petitioner believes that the correction cannot be made within this time frame, it must notify the Agency. If, after 14 days the petitioner has not responded, the petition will be treated as if it has been withdrawn and the original fee, less $7,500 for handling and initial review, would be returned.

(2)(i) If, after the Agency's scientific review has begun and a submission has been determined to be scientifically deficient, such that additional data are required or any other significant issue arises that prevents the continuation of the scientific review or the Agency from making a regulatory decision, a resubmission fee shall be imposed. Petitioners have up to 75 calendar days from the date of EPA notification to correct the deficiency without penalty, after which an additional 35 percent of the original fee will be charged. The resubmission fee would be required at the time the requested studies and/or other material is submitted. If the petitioner believes that the correction cannot be made within this time frame, it must notify the Agency. If, after 75 days the petitioner has not responded, or subsequently fails to submit the required material within the negotiated time frame, the petition will be treated as if it has been withdrawn. The original fee will not be returned.

(ii) A deficiency that would warrant the resubmission fee would include a study that is not fully acceptable and must be repeated in whole or in part (*e.g.*, a toxicology study that is categorized as ''non-upgradable''), or any other significant issue that prevents the continuation of the scientific review or the Agency from reaching a regulatory decision.

(e) *Fee waivers.* (1) No fee under this section will be imposed for any of the following actions:

(i) A petition submitted by the Inter-Regional Research Project Number 4 (IR–4 Program).

(ii) A minor use tolerance action, except when the minor use constitutes the first food use or the sole use of an existing chemical.

(iii) A biopesticide tolerance action, except for a plant-pesticide.

(iv) A petition for an emergency exemption tolerance under FFDCA section 408(l)(6).

(v) A petition to revoke a tolerance or a tolerance revocation.

(vi) Other ingredients generally regarded as safe (List 4A inerts).

(vii) Tolerance exemptions for chemicals exempted from regulation under section 25(b) of FIFRA.

(2) The Administrator may waive or refund part or all of any fee required by this section if the Administrator determines in his or her sole discretion that such a waiver or refund will promote the public interest, or that payment of the fee would result in an unreasonable economic hardship on the person required to remit the fee.

(i) A request for a fee waiver or refund must be submitted to the Agency in writing and must adhere to Agency criteria for tolerance fee waiver or refund requests. A fee of $7,500 shall accompany every waiver or refund request. The fee will be returned if the request is granted. Conversely, the fee will be forfeited if the request is denied.

(ii) A petition or tolerance reassessment action for which a waiver of the fee has been requested will not be acted upon until the fee has been waived, or if the waiver has been denied, the proper fee is submitted. A request for a refund will not be accepted after scientific review has begun.

(3) For the purposes of this section, EPA defines a minor use as any crop use other than that on alfalfa, almonds, apples, barley, beans (dry and snap), canola, corn (field, sweet, or pop), cottonseed, grapes, hay, pecans, potatoes, rice, rye, sorghum, soybeans, sugarbeets, sugarcane, sunflower, oats, oranges, peanuts, tomatoes, or wheat.

(4)(i) Fees for petitioned tolerance exemptions for other ingredients to be added to List 4A are to be refunded when it is determined by the Agency that the List 4A designation is warranted.

(ii) The most current listing of List 4A inerts can be found posted on the Internet on EPA's home page at http://www.epa.gov/opprd001/inerts/lists.html, or by writing Registration Support Branch (Inerts), Registration Division (Mail Code 7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

(5) Fees for petitioned tolerance exemptions for active ingredients to be added to the list of chemicals exempted from regulation under FIFRA section 25(b) will be refunded when it is determined by the Agency that the 25(b) designation is warranted. The list of FIFRA exempted substances can be found in 40 CFR 152.25.

(f) *Objections, hearings, or requests for administrative review.* (1) Objections, hearings, or requests for administrative review filed under section 408(g) of the Federal Food, Drug and Cosmetic Act must be accompanied by a fee of $15,500.

(2) A person who files a requests for judicial review of an order under section 408(h) of the Federal Food, Drug and Cosmetic Act must pay the costs of preparing the record on which the order is based.

(3) A person may file a written request for a waiver of the objection fee in lieu of the objection fee. A waiver fee of $7,500 shall accompany the request only if the person has a financial interest in the matter. This waiver fee is not required to be remitted if the person does not have a financial interest in the matter.

(g) *Method of payment.* All deposit and fee payments required under this section must be paid by money order, bank draft, or certified check drawn to the order of the Environmental Protection Agency. All remittances must be sent to the U.S. Environmental Protection Agency, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Both the envelope and the payment must be specifically labeled ''Tolerance Fees'' and should include only a copy of the letter or petition requesting the tolerance or the tolerance reassessment filing form. The actual letter, petition, or form, along with supporting data must be forwarded within 30 days of payment to the Agency at its headquarters address in Washington, DC.

(h) *Changes to fee schedule.* (1) This fee schedule will be increased annually to reflect the annual increase in Federal salaries. When such changes are made based on the Federal General Schedule (GS) pay scale, the new fee schedule will be published in the **Federal Register** as a Final Rule to become effective 30 days or more after publication, as specified in the rule.

(2) Agency tolerance processing costs and existing fee amounts will be reviewed periodically to ensure that revenues collected are adequately covering the costs incurred. If, as a result of this review, adjustments in the fee schedule are warranted, the changes will be subject to public notice and comment procedures.

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