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Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's rules and regulations. All such motions or protests should be filed on or before June 15, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 95-14478 Filed 6-13-95; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-5221-2]

Agency Information Collection Activities Under OMB Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected cost and burden; where appropriate, it includes the actual data collection instrument.

DATES: Comments must be submitted on or before July 14, 1995.

FOR FURTHER INFORMATION OR A COPY CALL: Sandy Farmer at EPA, (202) 260-2740, and refer to EPA ICR No. 0226.12.

SUPPLEMENTARY INFORMATION:

Office of Water

Title: Applications for the National Pollutant Discharge Elimination System (NPDES) Permit and the Sewage-Sludge Management Permit (OMB Control No. 2040-0086; EPA ICR No. 0226.12). This is a request for extension of a currently approved information collection.

Abstract: Under the Clean Water Act, EPA or a delegated State regulatory

authority issues permits to facilities discharging pollutants into the waters of the United States under the National Pollutant Discharge Elimination System (NPDES) program. The Act also authorizes EPA to issue permits for the use and disposal of sewage sludge. Most information is supplied on standard application forms, with different forms corresponding to different types of applicants. This ICR includes justification for all the information requirements relating to facilities applying for such permits.

Burden Statement: The public reporting and recordkeeping burden for this collection of information is estimated to average 7 hours per respondent. This estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information.

Respondents: Facilities that discharge wastewater or use or dispose of sewage sludge.

Estimated No. of Respondents: 101,988.

Estimated Total Annual Burden on Respondents: 622,628 hours.

Frequency of Collection: On occasion. Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to the following addresses. Please refer to EPA ICR No. 0226.12 and OMB Control No. 2040-0086 in any correspondence.

Ms. Sandy Farmer, EPA ICR No. 0226.12, U.S. Environmental Protection Agency, OPPE Regulatory Information Division (2136), 401 M Street SW., Washington, DC 20460 and

Mr. Tim Hunt, OMB Control No. 2040-0086, Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th Street NW., Washington, DC 20503.

Dated: June 1, 1995.

Joseph Retzer,

Director, Regulatory Information Division.

[FR Doc. 95-14547 Filed 6-13-95; 8:45 am]

BILLING CODE 6560-50-M

[OPPTS-00171; FRL-4961-8]

Uniform Reporting of Environmental Data; Facility Key Identifiers Open Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Open Meeting.

SUMMARY: EPA has established the Facility Key Identifiers Project to

streamline access to and development of a uniform reporting structure for environmental data. The Facility Key Identifiers Project Staff of the Office of Pollution Prevention and Toxics, is announcing a public meeting to discuss the scope of the project and anticipated proposed regulations.

DATES: The meeting will be held on June 23, 1995. The first session will be held from 9 a.m. to 11 a.m. and the second session will be held from 1 p.m. to 3 p.m. The agenda for both sessions will be the same, although the first will be focussed more on environmentalist and public access issues, while the second will be focussed on industry reporting issues.

ADDRESSES: The meeting will be held at the Environmental Protection Agency, 401 M St., SW., Washington, DC in the Washington Information Center, room North 3.

FOR FURTHER INFORMATION CONTACT: Diane Sheridan, Office of Pollution Prevention and Toxics (7407), US Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, telephone: (202) 260-3435. E-mail, sheridan.diane@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has established the Facility Key Identifiers Project to streamline access to and develop a uniform reporting structure for environmental data by establishing a uniform set of "place-based" identifier information for use by EPA, State environmental agencies, and the public. The scope of the project, proposed structure of the Key Identifiers, anticipated proposed regulations and the infrastructure needed to make the system operational will be discussed at the meeting.

List of Subjects

Environmental protection.

Dated: June 9, 1995.

Steven D. Newburg-Rinn,

Acting Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 95-14678 Filed 6-13-95; 8:45 am]

BILLING CODE 6560-50-F

[OPP-260055; FRL-4944-2]

Pesticide Tolerances; Partial Response to Petition to Modify EPA Policy

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; Response to Petition.

SUMMARY: This notice responds in part to a petition filed with EPA by the

National Food Processors Association and other food and grower trade associations. That petition sought the repeal or revision of several EPA policies and interpretations related to how EPA coordinated actions under its various statutory authorities over pesticide residues in food. EPA regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act and sections 408 and 409 of the Federal Food, Drug, and Cosmetic Act. Although EPA has not resolved all of the policy questions raised by the NFPA petition, EPA has concluded that changes are warranted to its policy concerning when FFDCA section 409 is applicable to a pesticide use and several related legal interpretations.

FOR FURTHER INFORMATION CONTACT: By mail: Niloufar Nazmi, Special Review and Reregistration Division (7508W) or Jean Frane, Policy and Special Projects Staff (7501C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Telephone numbers: 703-308-8028 or 703-305-5944; e-mail: nazmi.niloufar@epamail.epa.gov. or frane.jean@epamail.epa.gov.

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I. Introduction

In *Les v. Reilly*, 968 F.2d 985 (9th Cir. 1992), cert. denied, 113 S.Ct. 1361 (1993), the Ninth Circuit U.S. Court of Appeals held that the Delaney anti-

cancer clause in the food additives provision of the Federal Food, Drug, and Cosmetic Act was not subject to an exception for pesticide uses which pose a *de minimis* cancer risk. Prior to the decision becoming final, food processors and growers filed a petition with EPA challenging a number of policies and interpretations relating to how EPA implements its authority under the FFDCA. The petition proposes policies and interpretations that would reduce the impact of the *Les* decision. This notice responds to the petition in part.

II. Background

A. Statutory Background

Pesticide residues in human and animal food in the United States are regulated under provisions of the Federal Food, Drug and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The interplay between sections 402, 408 and 409 of the FFDCA and, to a more limited extent, between the FFDCA and FIFRA, have created a complex, and sometimes contradictory, statutory framework underlying residue regulation in food.

Before a pesticide may be sold or distributed, it must be registered under the FIFRA. 7 U.S.C. 136 et seq. To qualify for registration, a pesticide must, among other things, perform its intended function without causing "unreasonable adverse effects on the environment." 7 U.S.C. 136a(c)(5). The term "unreasonable adverse effects on the environment" is defined as "any unreasonable risk to man or the environment taking into account the economic, social and environmental costs and benefits of the use of any pesticide." 7 U.S.C. 136(bb).

The FFDCA, 21 U.S.C. 301 et seq., authorizes the establishment by regulation of maximum permissible levels of pesticides in foods. Such regulations are commonly referred to as "tolerances." Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is "adulterated" under section 402 of the FFDCA and may not be legally moved in interstate commerce. 21 U.S.C. 331, 342. EPA was authorized to establish pesticide tolerances under Reorganization Plan No. 3 of 1970. 5 U.S.C. App at 1343 (1988). Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA).

The FFDCA has separate provisions for tolerances for pesticide residues on

raw agricultural commodities (RACs) and for residues on processed food. For pesticide residues in or on RACs, EPA establishes tolerances, or exemptions from tolerances when appropriate, under section 408. 21 U.S.C. 346a. EPA regulates pesticide residues in processed foods under section 409 which pertains to "food additives." 21 U.S.C. 348. Maximum residue regulations established under section 409 are commonly referred to as food additive tolerances or food additive regulations (FARs). Section 409 FARs are needed, however, only for certain pesticide residues in processed food. Under section 402(a)(2) of the FFDCA, a pesticide residue in processed food generally will not render the food adulterated if the residue results from application of the pesticide to a RAC and the residue in the processed food when "ready to eat" is below the RAC tolerance set under section 408. This exemption in section 402(a)(2) is commonly referred to as the "flow-through" provision because it allows the section 408 raw food tolerance to flow through to the processed food form. Thus, a section 409 FAR is only necessary to prevent foods from being deemed adulterated when the concentration of the pesticide residue in a processed food when "ready to eat" is greater than the tolerance prescribed for the RAC, or if the processed food itself is treated or comes in contact with a pesticide.

To establish a tolerance regulation under section 408, EPA must find that the regulation would "protect the public health." 21 U.S.C. 346a(b). In reaching this determination, EPA is directed to consider, among other things, the "necessity for the production of an adequate, wholesome, and economical food supply." *Id.* Prior to establishing a food additive tolerance under section 409, EPA must determine that the "proposed use of the food additive [pesticide], under the conditions of use to be specified in the regulation, will be safe." 21 U.S.C. 348(c)(3). Section 409 specifically addresses the safety of carcinogenic substances in the so-called Delaney clause which provides that "no additive shall be deemed safe if it has been found to induce cancer when ingested by man or animal or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal * * *." *Id.* Although EPA has interpreted the general standard under section 408 to require a balancing of risks and benefits, where a pesticide which is an animal or human carcinogen is involved, the section 409

Delaney clause, in contrast to section 408 and FIFRA, explicitly bars such balancing no matter how infinitesimal the potential human cancer risk. *Les v. Reilly*, 968 F.2d at 989.

B. EPA Coordination of the Statutory Provisions Governing Pesticides

In its administration of FIFRA and FFDC sections 408 and 409, EPA has specified that FIFRA registrations for food-use pesticides will not be approved until all necessary tolerances and food additive tolerances have been obtained. 40 CFR 152.112(g). As a policy matter, EPA has taken a similar approach to FFDC sections 408 and 409, not granting section 408 tolerances until needed section 409 FARs have been granted.

This linkage of its statutory authorities has been described by EPA as its coordination policy. Basically, EPA's coordination policy is an expression of EPA's intent to take into account all of the applicable provisions governing pesticides in taking action under any one of the three. EPA's view has been that it should not be approving pesticide uses under one of the three provisions if an approval needed under one of the other provisions cannot be obtained.

EPA's concentration policy establishes the criterion as to when approval is needed for food-use pesticides under FFDC section 409, and hence when the Delaney clause applies. Generally, EPA has used a "concentration in fact" standard as the test of whether a use needs a section 409 FAR. The concentration in fact standard focuses on the level of the pesticide residue in the processed food, measured on a weight to weight basis, compared to the level of the residue in the precursor raw agricultural commodity. If a processing study shows that the level of pesticide residue in the processed food exceeds the level of residue in the precursor raw agricultural commodity, EPA would conclude there has been a concentration in fact of the pesticide residues in the processed food.

EPA believes the concentration in fact test is relevant to the inquiry of whether a section 409 FAR is needed because residues in the raw crop may be at or near the section 408 tolerance level. Residues in the raw crop may be close to the section 408 tolerance level because section 408 tolerance levels are established based on actual field trials and designed to be set no higher than necessary given approved usage directions for the pesticide established in the FIFRA registration. Under EPA regulations, the section 408 tolerance level should "reasonably reflect the

amount of residue likely to result when the pesticide chemical is used in the manner proposed." 40 CFR 180.4. If residue levels in the raw crop are at or near the section 408 tolerance level and concentration in fact occurs during processing, the residue level in the processed food is likely to exceed the section 408 tolerance. The National Academy of Sciences (NAS) has acknowledged the logic behind EPA's reliance on a concentration in fact standard:

In determining whether a section 409 food additive tolerance is required, the EPA focuses on whether residues in any processed product exceed those found on the unprocessed crop, not whether residues concentrate above some hypothetical section 408 tolerance.

The logic of the EPA's practice is clear. A section 408 tolerance represents a residue level that may in some cases be realized. A section 409 tolerance must reflect the possible residue levels in processed foods derived from that raw commodity.

National Research Council, *Regulating Pesticides in Food: Delaney Paradox 28* (1987).

III. The NFPA Petition

On September 11, 1992, the National Food Processors Association (NFPA), the United Fresh Fruit and Vegetable Association, the Florida Fruit and Vegetable Association, the Northwest Horticultural Council, and the Western Growers Association filed a petition with EPA challenging the policies followed by EPA in linking its regulatory activities under the various pesticide provisions of FIFRA and FFDC. (Petition to the Environmental Protection Agency, Office of Pesticide Programs, Concerning EPA's Pesticide Concentration Policy (1992)) (hereinafter cited as "NFPA petition"). The NFPA petition explicitly attacks what it calls EPA's "concentration policy." In actuality, the petition is a challenge to two interrelated policies described by EPA as its coordination and concentration policies. The NFPA petition argues that the coordination and concentration policies are both unlawful and unnecessary. The petition requests that the EPA coordination policy be repealed so that section 408 tolerances can remain in effect (or can be established) for pesticide uses even if, under the *Les* decision, the associated section 409 FARs have to be revoked (or cannot be established). The petition asks that the concentration policy be modified so that it takes into account factors beyond the concentration in fact test. Additionally, the petition requests that EPA apply the term "ready to eat" in the flow-through provision according

to what NFPA asserts is its plain meaning.

EPA sought public comment on the petition (58 FR 7470, Feb. 5, 1993). Extensive public comment was received, and significant comments are discussed in this notice. Several more narrowly focused comments are discussed in a separate document that has been included in the docket.

IV. Summary of EPA's Partial Response to NFPA Petition

Sections V through VII below set forth EPA's partial response to the NFPA petition. EPA has not reached a decision on NFPA's challenge to the coordination policy. EPA, however, has completed evaluation of NFPA's contentions regarding the concentration policy and EPA's interpretation of the term "ready to eat." This document responds to the NFPA petition on these two issues. In brief, EPA agrees with NFPA and many of the commenters that modifications should be made to its concentration policy so that it is a better predictor of the likelihood that residues in processed food may exceed the applicable section 408 tolerance. EPA, however, cannot accept all of NFPA's suggested changes to the concentration policy. As to interpretation of the phrase "ready to eat," EPA agrees that such term must be given its common-sense meaning.

V. Concentration Policy

A. General Issues

EPA's concentration policy is the trigger for when a pesticide use needs a section 409 FAR. EPA has treated a pesticide use as needing a section 409 FAR generally whenever a processing study shows that pesticide residues are greater in the processed food than in the raw agricultural commodity before processing. In other words, EPA looks to see if the pesticide "concentrates in fact." EPA has used concentration in fact as the trigger for when a food additive regulation is needed because, in theory, RAC tolerances are set at levels no higher than necessary to cover maximum legal usage under the FIFRA registration. RAC tolerances are established based on field trial data showing the range of residues likely to result from maximum legal application of the pesticide. Generally, the RAC tolerance level is set just slightly above the maximum residue value found in the field trials. Thus, if concentration in fact occurs during processing, overtolerance residues in processed food can result if the RACs used for processing contain pesticide residues reflecting maximum legal usage.

NFPA challenges EPA's concentration policy on two grounds. First, NFPA claims that all available data support the view that food additive regulations are unnecessary to avoid adulterated processed food. Second, NFPA argues that EPA has ignored the "ready to eat" requirement in the flow-through provision. EPA's interpretation of the term "ready to eat" will be addressed in the following section.

B. Monitoring Data and the Concentration Policy

NFPA cites various data sources which it claims show residues on both raw and processed foods generally to be well below the level of the RAC tolerance. NFPA argues that residues in processed foods generally fall below RAC tolerances because of the careful attention paid to the flow-through provision by food processors.

When the flow-through provision was adopted and as it operated for a number of years, processors clearly understood that it was their obligation to produce a processed product that stayed within the raw product tolerance. This obligation could be met through any number of steps, including supervision of growers' pesticide practices, careful and informed buying practices, analysis of raw product, handling, cleaning and treatment of the raw product, and testing of the finished produce to assure that it would be in compliance with the Act * * *. [T]hey recognized that if their process involved some degree of concentration [and the food is consumed in the concentrated form], they were well advised to use raw product that at the time of processing was below the prescribed tolerance levels, and that failure to take such steps could possibly result in adulteration and a costly enforcement action.

(Comments of NFPA at 37-38).

NFPA asserts that the steps taken by processors to avoid overtolerance residues show that EPA's reliance on processing studies to require food additive regulations is unwarranted.

The data relied upon by NFPA do show that pesticide residues in raw and processed food generally are below section 408 tolerance levels. On the other hand, EPA is often presented with processing studies by pesticide manufacturers that demonstrate that particular pesticides concentrate in processed food to levels 2 times, 10 times, or even 50 times above the level found in the raw crop. EPA has examined carefully the factors cited by NFPA and commenters as an explanation for the low levels of residues to determine whether any adjustments to the concentration policy are appropriate. Although EPA has concluded that some adjustment to the concentration policy is warranted, EPA

believes that the basic rationale of the concentration policy with its focus on concentration in fact is sound. As the National Academy of Sciences has found:

The logic of EPA's practice is clear. A section 408 tolerance represents a residue level that may in some cases be realized. A section 409 tolerance must reflect the possible residue levels in processed foods derived from that commodity.

National Research Council, *Regulating Pesticides in Food: Delaney Paradox* 28 (1987)

At the same time, EPA recognizes that reliance solely on processing studies may not, in some circumstances, accurately "reflect the possible residue levels in processed foods."

In challenging the concentration policy, some commenters argue that EPA's policy is a theoretical exercise with no basis on actual data and that this is confirmed by EPA's description of its policy in its request for comment on the NFPA petition. EPA did not mean to suggest in that notice that its concentration policy focuses on theoretical possibilities. EPA's policy has always sought to determine whether residues greater than the section 408 tolerance can occur in processed food. EPA makes this determination based on hard data— actual processing studies involving, in most cases, the pesticide and crop in question. EPA's revisions to its policy do not change the basic focus of the concentration policy. Rather, as explained below, EPA has expanded the range of data and other information it will consider in determining whether residues greater than the section 408 tolerance can occur in processed food.

It is worth noting that the same data relied upon by NFPA to show that most food, whether raw or processed, is well below section 408 tolerance levels also reinforces EPA's judgment that many section 408 tolerances may currently be set higher than necessary and may need to be lowered so that they reasonably reflect actual residues. If section 408 tolerances are lowered, the chances of residues over the section 408 tolerance in processed foods where residues concentrate in fact would be greater.

C. Revisions to the Concentration Policy

1. *Introduction and summary.* EPA's concentration policy is designed to evaluate when residues in processed food may exceed the raw food tolerance due to concentration during processing. Generally, in implementing its concentration policy, EPA has used a test of concentration in fact as an indicator that residues over the section 408 tolerance may occur because residue levels in the RAC may exist at

the tolerance level. EPA, however, also has historically considered, to a limited extent, at least two other factors in evaluating whether a processing study showing concentration of residues indicates there is a real possibility of residues over the section 408 tolerance. Below, EPA discusses those factors and other factors that may prevent the occurrence of residues over the section 408 tolerance.

EPA concludes that it has too rigidly applied its concentration in fact test. EPA continues to believe that information from processing studies is generally the most important single piece of information is assessing the likelihood that residues in processed food could exceed the section 408 tolerance. EPA will also continue to consider factors such as the variability of the analytical method and the degree of rounding used in establishing the section 408 tolerance. In a departure from past practice, EPA will, as explained below, take into account, where appropriate, information pertaining to the averaging of residues during processing. EPA will also, where appropriate, consider information obtained from properly designed market basket surveys. EPA, however, is not convinced at this time by the NFPA suggestion that, despite data showing residues concentrate during processing, processors can insure residue levels stay below section 408 tolerance levels.

2. *Factors relied upon by EPA in determining whether a pesticide which concentrates in fact is likely to produce residues in exceedance of the section 408 tolerance.* As noted, EPA follows a concentration in fact test to determine if section 409 FARs are necessary. For the most part, EPA's concentration in fact test is applied based on the results from data from processing studies. Historically, EPA has also occasionally considered two other factors in determining whether a processing study which shows concentration in fact does show that residues in processed food can exceed the appropriate section 408 tolerance.

The first of these factors is the degree of rounding that was used in setting the RAC tolerance. To a limited extent, EPA has considered the degree of rounding in past decisions on whether a section 409 FAR is needed. Generally, the highest value obtained from field trials is rounded up in selecting the tolerance level. For example, if the highest value from field trials was 8 parts per million (ppm), that data point might be rounded to 10 ppm for the tolerance value. Where rounding increases the observed residue level by 25 percent, the pesticide would have to concentrate by

a factor of greater than 25 percent (1.25X) to produce residues over the section 408 tolerance.

The second factor currently relied upon by EPA is the degree of variability in the analytical method used to measure residue levels in the field and processing studies and for enforcement of the tolerance. If residues do not concentrate to a greater degree than the variability in the methods, no residues over the section 408 tolerance could be reliably detected.

3. *Other factors potentially relevant to whether residues exceed the section 408 tolerance.* In the past, EPA has generally not taken into consideration various other factors that may explain why, despite the fact that a processing study suggests there is a possibility of residues greater than the RAC tolerance, that event seems to occur infrequently. One factor that lessens the possibility of residues over the section 408 tolerance in processed food is that EPA's judgment concerning whether such residues could occur assumes that the pesticide will be used at the maximum label rate and applied the maximum number of times permitted, and that the crop will be harvested at the shortest preharvest interval allowed. Frequently, however, these maximum application and harvest practices are not followed resulting in residues far below tolerance levels in the raw crop, with correspondingly lower levels in the processed food.

A second factor that serves to result in lower residue levels is that tolerance values are set to reflect the maximum residue level that could result from maximum legal application and harvest practices but field trials generally show a wide range of residue levels even when maximum legal application and harvest practices used in each trial. Thus, average residue values from such field trials tend generally to be significantly below the maximum residue level found in field trials and, thus, also significantly below the tolerance level.

A third factor that may explain lower observed residues in processed foods is that the processing of many crops involves mixing or blending of large amounts of the raw crop. Oftentimes this can result in significant lowering of residue values as untreated crop is blended with treated crop. Further, this blending accentuates the above two factors as lightly treated crops are mixed with crops having received maximum treatment and high and low level residues from crops receiving maximum treatment are mixed.

Another reason why residues over the section 408 tolerance may not occur in

processed food is that pesticides often degrade significantly during the time in which the crop is transported and stored prior to processing. Thus, even if crops bearing tolerance level residues at harvest were the only ingredient used in food processing, any concentration of residues might be offset by normal degradation of residues.

NFPA suggests additionally that the chance of residues over the section 408 tolerance is not great because of various steps taken by food processors. NFPA cites "supervision of growers' pesticide practices, careful and informed buying practices, [and] analysis of raw product" as actions which serve to reduce residues. Further, various commenters have contended that residues over the section 408 tolerance in some processed foods could be avoided by restrictions on pesticide use to crops grown for the fresh market.

4. *Evaluation of factors.* Below, EPA evaluates its concentration policy including EPA's use of processing studies, the factors considered by EPA in evaluating whether processing studies show the possibility of residues over the section 408 tolerance, and the relevance of the various reasons noted above why overtolerance residues infrequently occur.

Processing studies. EPA guidelines on residue data specify that processing studies should "simulate commercial processing as closely as possible." Pesticide Assessment Guidelines, Subdivision O at 21 (1982). Data from such studies, EPA believes, remain the most relevant information in determining whether residues over the section 408 tolerance may occur. Because section 408 tolerance values represent a level of residues which field trial studies show can occur, data from a processing study showing concentration can be a good indicator regarding the possibility of overtolerance residues in processed food. EPA has not issued extensive industry-by-industry guidance on what constitutes "commercial processing" but rather has left it to the pesticide manufacturer to insure that modern commercial processing is reflected in the processing studies. Thus, EPA disagrees with comments by NFPA and other commenters which suggest it is EPA which is at fault for not taking into account practices such as washing and peeling that routinely occur during processing. If those practices are a part of commercial processing for certain foods and are not reflected in the processing studies designed and submitted by pesticide manufacturers, the pesticide manufacturers need to

provide EPA with data that are truly representative of the industry practice.

Rounding. To a limited extent, EPA has considered the rounding up that occurs in the selection of the section 408 tolerance value in making concentration determinations. EPA believes the degree of rounding remains a legitimate consideration in determining the likelihood that processing may produce residues in processed food greater than the section 408 tolerance. Moreover, as noted below, EPA believes it is appropriate to consider the difference between residue levels that can occur on crops and the section 408 tolerance level in evaluating the possibility of residues over the section 408 tolerance in processed food.

But EPA is concerned that its past practice of rounding up has resulted in section 408 tolerances being set at a level higher than is necessary to cover legally treated crops. EPA is currently examining whether older section 408 tolerances have been set at inappropriately high levels owing to rounding or for other reasons. EPA is also exploring whether there might not be statistical techniques for better assigning section 408 tolerance levels. To the extent EPA alters its approach to selecting section 408 tolerance levels, these revised section 408 levels will need to be considered in making determinations under the concentration policy.

Variability of methods. EPA continues to believe that the variability of the analytical method should be evaluated in determining whether residues over the section 408 tolerance are likely to be reliably detected despite a processing study showing concentration in fact. The aim of the concentration policy is to identify those uses which can produce residues over the section 408 tolerance in processed food. If any possible concentration is so low that it could not be clearly identified by the relevant analytical method, then, in fact, instances of residues over the section 408 tolerance in processed food would not be expected. The degree of variability in analytical methods must be assessed on a case-by-case basis. Generally, the variability in analytical methods suggests that residues over the section 408 tolerance are not likely to be reliably detected where processing studies show concentration factors in the range of 1.1X to 1.5X.

Treatment rates and processor control. EPA believes that it is appropriate to assume that some growers will treat a portion of their crop at the maximum treatment rate allowed by the label. EPA's experience has shown that due to unexpected weather

and pest pressures it is unrealistic to assume that no grower will treat his or her crop with a pesticide in the manner that yields the highest lawful residues.

Moreover, where residues do concentrate during processing, EPA questions the ability of the processor or grower to manage pesticide residue levels so as not to produce over-tolerance residues in processed food. Although processors may know the concentration factor of residues from processing studies, the concentration factor does not suggest with any precision how processors could instruct growers to change their pesticide application procedures so that residues over the section 408 tolerance will not result in processed food. Levels of residues in raw crops are dependent not only on how much pesticide is applied but on when and how the pesticide is applied. Little data exist that describe the effect of varying any of these procedures on residue levels. Similarly, EPA believes little information is available concerning how changes in their manufacturing processes affect residue levels in processed food. Finally, as discussed below, the comments received on the NFPA petition reinforce EPA's experience that farmers often do not know the ultimate destination of their crop. Therefore, EPA believes it would be very difficult for growers or processors to manipulate residue levels in processed food.

EPA would be open to considering further industry proposals laying out a potential policy framework that more specifically delineates how processor practices could be taken into account in determining the likelihood that residues in processed food would exceed the applicable section 408 tolerance. It would be helpful if such policy proposals contained criteria for evaluating whether specific processor claims regarding pesticide/commodity combinations are reasonable. Among other things, these criteria should address (1) what data would be submitted to EPA to verify residue levels, (2) how the practicality of the proposed scheme would be evaluated (e.g., degree of concentration of processing operations and ability to separate raw food streams), and (3) whether processor control of residue levels for a specific pesticide/commodity combination could be feasibly enforced. If such further policy proposals are received, EPA would seek public input before making any decision on the merits of the proposals and using the proposed criteria in evaluating specific pesticide uses.

Mixing and blending. EPA believes that in many instances it would be

appropriate to take into account mixing and blending in determining the likelihood that residues over the section 408 tolerance could result. This change in practice is warranted, EPA believes, because EPA's prior assumption, i.e., that all raw food have the potential to have residues at or near the section 408 tolerance level, does not adequately take into account the realities of food processing. Because of the way EPA sets section 408 tolerances, individual raw commodities do have the potential of having residues at or near the tolerance level. The data from field residue trials show, however, that residue values even from a single field can vary significantly. When individual raw commodities are mixed in processing operations, it is realistic to expect that there will be an averaging effect on the residues in the processed food.

Accordingly, if EPA determines that there is a sufficient degree of mixing or blending during processing such that the normal variation among individual samples from a field will be substantially evened out, EPA will consider comparing some "average" residue value from field trials times the concentration factor to the RAC tolerance level in determining the likelihood of residues over the section 408 tolerance. EPA generally believes that the most relevant "average" residue value from crop field trials is the highest average residue value from the series of individual field trials. Using an average of all samples from all field trials in all regions of the U.S. would tend to suppress the variability in residue values to a greater extent than can be expected by mixing or blending. Generally, crops grown in different regions of the U.S. are not mixed prior to processing. Rather, crops are often processed field-by-field as they are harvested by the grower.

There are a number of constraints EPA thinks are critical here. First, considering average field trial residues is only appropriate where the values being averaged are from field trials involving maximum treatment rates. In other words, averaging may be used to take into account the variation in residues which occurs in crops receiving maximum treatment and minimum preharvest intervals but not residue variations as result of different levels of treatment. As laid out above, EPA has no basis on which to make assumptions about whether crops in specific instances would be treated at rates lower than the maximum permitted on the pesticide label or what residues those lower rates would produce. Second, whether considering blending would be appropriate would

depend on the quality of the data base. Consideration of any "average value" would be less appropriate where adequate data from all representative regions of the country are not available. Finally, even where it would be appropriate to consider average residues, EPA believes a simple calculation showing that the average residue multiplied by the concentration factor from a processing study is less than the RAC tolerance alone may not conclusively show that residues over the section 408 tolerance could not result. In appropriate circumstances, EPA may need to consider a number of other factors, such as the variability in the field trial data, in determining the likelihood of residues over the section 408 tolerance.

Degradation of residues. Although EPA recognizes that degradation of residues frequently occurs, it is not apparent how EPA could take that phenomenon into account in its concentration policy other than to the extent the effects of degradation are captured in processing studies. EPA would need detailed data on the degradation rates of pesticides as well as on the minimum time between the harvesting of crops and when such crops are manufactured into ready-to-eat processed foods. Without such information, it would be difficult to establish a tolerance level that would assure that legally treated crops did not result in illegal food.

Some comments filed in response to the NFPA petition suggest that marketplace survey or FDA monitoring data would be relevant to whether there is a likelihood of residues over the section 408 tolerance. Certainly, data from marketplace studies have some degree of relevance to the question of whether residues in processed food may exceed the section 408 tolerance. The relevance of marketplace studies, however, depends on how the marketplace study was performed. For example, the principal reason marketplace studies have been conducted in the past is to obtain better data concerning actual residue values close to the point at which food is consumed. Thus, marketplace studies generally involve sampling commodities in retail grocery stores. A tolerance for processed food would not only apply to food in retail stores but at all prior points at which the food moved in interstate commerce. This fact would have to be taken into account in assessing the relevance of a marketplace study in determining the likelihood of residues in processed food in excess of the section 408 tolerance. Monitoring data can also be relevant to determining

the likelihood of residues in processed food exceeding the section 408 tolerance. However, FDA monitoring data, especially monitoring data on processed foods, generally has been limited and thus may not be a reliable predictor of the level of residues of a particular pesticide in a particular processed food.

Market segregation. Several commenters contend that, even where residues could be expected to concentrate in processed food above the section 408 tolerance, if EPA were to permit pesticides to be labeled solely for crops grown for fresh market, no section 409 FAR would be needed for such pesticide uses. These commenters claim that certain crops are so specialized that they are grown specifically for the fresh or processed market, and, in some instances, that even different pesticides are used on crops depending on whether they are intended for the fresh or processed market. Thus, these commenters argue that allowing pesticides to be labeled for crops grown only for the fresh market where a specialized crop has been developed solely for the fresh market would not pose an enforcement problem. On the other hand, EPA received other comments stating that placing such label restrictions on pesticides would subject growers to a form of "Russian Roulette." EPA's observations indicate that it is difficult to achieve total market segregation; however, if a party can show that a market for a specific crop can be segregated and that such segregation can be feasibly monitored, EPA will not require a section 409 FAR for a pesticide on that crop.

5. *Conclusion.* In sum, EPA's concentration policy will continue to focus on "possible residues" in the processed food. EPA will place primary emphasis on whether processing studies show that the processing of a commodity results in a level of residues in the processed food which is greater than the level of residues in the raw food. EPA will also consider the variability of the analytical method, the degree of rounding involved in establishing the section 408 tolerance, and, where circumstances permit, information concerning blending of crops and average field trial values, and market basket surveys. EPA will consider information concerning potential market segregation and pesticide segregation, but such segregation must be established by clear evidence. But EPA remains unconvinced at this time that it should give much weight at all to degradation information or the possibility that farmers are applying pesticides at lower

application rates or that processors will control whether residues over the section 408 tolerance occur.

VI. Ready To Eat

A. NFPA's Argument and Views of Commenters

The NFPA petition argues that EPA has failed to take into account language in the flow-through provision of FFDCA section 402 specifying that processed food is to be evaluated at the "ready-to-eat" stage in determining whether the food exceeds the relevant section 408 tolerance. According to NFPA, the "ready to eat" language was added to the statute to "take care of any particular problem that might be raised with respect to a product that was concentrated or dehydrated." (NFPA Petition at 34). In its comments, NFPA proposed a definition of not ready-to-eat food as food "customarily reconstituted by the consumer or food manufacturer, or [food] sold for use as an ingredient in the preparation of finished foods." (Comments of NFPA at 12). Further, NFPA cites several examples from the Code of Federal Regulations and the **Federal Register** in which Federal agencies have used the term "ready to eat" to distinguish between various foods.

Except for two comments from State agencies (Florida Department of Agriculture and North Dakota Department of Agriculture), most of the commenters on the NFPA petition assert that EPA's approach of treating any food available for sale as "ready to eat" is violative of the plain words of the statute. Many of these commenters also contend that EPA overstated the enforcement difficulties of construing the term "ready to eat" more narrowly.

As to the definitional issue, numerous commenters contend that the literal or plain meaning of the term "ready to eat" food is food consumed "as is." One commenter quotes the dictionary definitions of "ready" and "eat" to derive a definition of "ready to eat" food as "prepared for immediate taking through the mouth as food." (Comments of Catherine Clay at 1). Many commenters mention specific foods and assert that they were not consumed "as is." In their comments, fruit growers are particularly adamant that juice concentrates are not "ready to eat." (See, e.g., comments of Sun-Diamond Growers at 7 ("People simply do not consume a quart of prune juice concentrate or even a cup of concentrate.")). Another commenter contends that EPA should focus on what the usual practice was as to foods:

We suggest that for those food items that are never or seldom consumed in their concentrated forms (e.g., tomato paste, oils, flour, and juice concentrates), Section 402 should be followed * * *. Those few situations in which product might be consumed in the concentrated form do not present an imminent hazard and will not add significantly to the risk calculation.

(Comments of Del Monte Foods at 1).

As to potential enforcement difficulties with following a consumed "as is" approach to "ready to eat," several commenters argue that EPA could adopt action levels to determine if processed not ready-to-eat food is adulterated. (Comments of Monsanto; Grocery Manufacturers Association; NFPA). Such action levels would be established using dilution factors that take into account the dilution of pesticide residues as a food is mixed with other foods in processing operations. The dilution factors, these commenters urge, should be based on the most concentrated form of ready-to-eat food that the not-ready-to-eat food was used to produce.

Finally, several commenters claim that commodities such as fruit pomaces and seed hulls which are commonly used as animal feeds are not "ready to eat." According to these commenters, most animal feeds are a blend of different ingredients because commodities such as pomaces and hulls are both nutritionally deficient and unpalatable.

B. EPA's Response

1. *The definitional issue.* EPA has considered NFPA's arguments and the comments received and has examined the previous uses of the term "ready to eat" by EPA and other Federal agencies. EPA agrees that the term "ready to eat" food has a common-sense meaning of food which is consumed without further preparation. EPA intends to apply that interpretation in future actions. Basically, EPA believes that food should be considered "ready to eat" if it is consumed "as is" or is added to other ready-to-eat foods (e.g., condiments). Use of this interpretation, of course, will not clarify all issues regarding "ready to eat" foods. EPA envisions that this definition may be difficult to apply in many instances.

Some foods will be easier to classify than others. EPA has, in the past, established section 409 FARs for some foods that clearly do not meet a common-sense interpretation of "ready to eat", and EPA did so without closely considering what level of residue would occur in derivative foods which are "ready to eat." Examples would include dried hops, mint oil, citrus oil, and guar

gum. These foods are not generally available to consumers in grocery stores and, even if a consumer could purchase such a food, it would not be consumed "as is" but would be further processed (e.g., dried hops used in brewing beer) or used as an ingredient in a food product. Other foods for which EPA has set food additive regulations, such as raisins, olives, and potato chips, clearly are "ready to eat."

EPA generally believes that foods that are mixed prior to consumption are not "ready to eat." Mixing generally involves the combining of foods with the intent of creating a different food product. For example, combining a tea bag with hot water is intended to create a new food product, the beverage tea. Thus, the dried tea in the tea bag would not be considered "ready to eat." On the other hand, EPA does not believe this mixing principle applies to condiments. Condiments are consumed as a supplement to other "ready to eat" food. A condiment is also consumed "as is."

There remain, however, many commodities for which EPA has traditionally set food additive regulations which are not so easily characterized under the "ready to eat" standard and which will require a case-by-case inquiry. One of the reasons for the fact-intensive nature of this inquiry is that foods have many uses and eating habits vary widely in the United States. Thus, determining whether a food is "ready to eat" involves identifying all significant uses of a food and then determining if any of those uses meets the definition of "ready to eat." For example, perhaps the most common use of vegetable oil is as a cooking medium or as an ingredient in baked products. However, another use of vegetable oil is as a "dressing" for a green salad. When used in this manner, oil is directly added to the salad as a condiment, and thus oil generally would qualify as "ready to eat." Additionally, EPA will need to explore whether some foods which have traditionally not been consumed without further preparation, are actually being consumed on an "as is" basis. Comments submitted by DuPont Agricultural Products support this approach:

We appreciate that some concentrated products can be consumed without mixing. The likelihood of occurrence of this consumption pattern is a factor which should be considered in determining which form is best viewed as the ready-to-eat stage. In our view, a reasonable approach would be to weigh such a consumption pattern based on the frequency of occurrence. If the consumption of the concentrate occurs with great infrequency, the appropriate ready-to-eat food would still be the diluted product.

(Comments of DuPont Agricultural Products at 8).

In circumstances where EPA's revised approach to the term "ready to eat" results in particular food forms of a commodity being dropped from the category of "ready to eat," EPA will need to explore whether there is a possibility of concentration of residues above the section 408 tolerance in any other, ready-to-eat forms of that commodity. In many instances further preparation of a not-ready-to-eat commodity will so significantly reduce residues that, even if the not-ready-to-eat precursor processed food contained residues over the section 408 tolerance, the ready-to-eat commodity will not. Use of citrus oil as a flavoring in ice cream may be an example of this phenomenon. Citrus oil may be such a small proportion of the total product that any residues over the section 408 tolerance in the oil would be diluted below the section 408 tolerance in the ice cream. However, in other instances, the dilution involved in further preparation of a not-ready-to-eat processed food is not so dramatic. For example, flour, assuming it is found to be a not-ready-to-eat food, is prepared into commodities such as crackers or tortillas in which the dilution factor may be fairly modest. In situations such as this, EPA will have to determine whether it should be setting section 409 FARs on different commodities than has been EPA's traditional practice.

2. Enforcement approach. EPA's revised approach to the term "ready to eat" will make enforcement of the FFDCa more challenging as regards foods no longer considered "ready to eat." EPA does not view as satisfactory NFPA's suggestion that for enforcement purposes EPA should develop dilution tables and from such tables promulgate action levels to evaluate the legality of not-ready-to-eat processed food. Although this is a possibility, EPA regards it as cumbersome and lacking the enforcement ease of binding tolerances. An action level is not binding on anyone and thus even though use of a dilution table may suggest that a food is adulterated, FDA could only successfully proceed against the food if it could prove in court that the level of residue found in the not-ready-to-eat food would render ready-to-eat food adulterated.

Instead, EPA has decided to use its general rule-writing authority under FFDCa section 701 to establish maximum residue levels for not-ready-to-eat processed food. Section 701 grants EPA the authority "to promulgate regulations for the efficient enforcement of this Act." 21 U.S.C. 371. These

maximum residue levels would be set no higher than the levels which could result in the processed food assuming legal residues in the raw food and that good manufacturing practices were followed.

EPA's authority to set such maximum residue levels arises from the flow-through provision. The flow-through provision does not legalize residues in ready-to-eat processed food unless three criteria are met: (1) the residues are at or below the applicable section 408 tolerance; (2) the precursor raw food had residues within the section 408 tolerance; and (3) good manufacturing practices were followed in preparing the processed food. The maximum residue levels set under section 701 would establish binding regulations as to when the two latter criteria of the flow-through provision are met for a specific pesticide use. If such a maximum residue level were exceeded in a processed food, then as a matter of law the flow-through provision would not apply to the food (whatever the residues in the food when it is "ready to eat"), and thus the food would be adulterated as a matter of law under FFDCa section 402(a)(2)(C).

3. Animal feeds. As noted, a number of commenters claimed that food processing byproducts such as grape pomace, soybean hulls, etc. are not "ready to eat" either because they are unpalatable or nutritionally deficient or because they are not a significant portion of the diet of animals. EPA generally intends to apply a similar approach to processing byproducts used as animal feeds as it will to human foods in determining whether the byproducts are "ready to eat" and will also use section 701 maximum residue levels, as described above, where appropriate. Determinations on specific processing byproducts will have to be made on a case-by-case basis. To the extent it can be shown that any individual processing byproduct is unpalatable when fed "as is" or that for other reasons the processing byproduct is generally not fed absent further processing or mixing, EPA would not categorize that particular byproduct as "ready to eat." EPA believes this showing probably can be made for a substantial number of processing byproducts.

In response to comments stating that EPA required examination of processing byproducts not currently used as animal feeds (e.g., apple pomace), EPA would note that it has recently revised its guidelines on what processing byproducts are used as animal feeds. This revision followed a comprehensive survey of animal feed practices. EPA has

also sought public comment on those guideline revisions and will continue to consider comments on this issue.

4. *Future actions.* EPA intends to apply its revised approach to the term "ready to eat" in all future tolerance actions. When any action is taken based on EPA's revised approach, EPA will seek public comment on designations for specific commodities prior to making any final determinations.

VII. Are EPA's Policies Rules That Have Not Been Properly Promulgated?

NFPA contends in its petition that EPA's coordination and concentration policies are not in compliance with the Administrative Procedure Act (APA) because they have not been promulgated as a binding regulation through notice and comment procedures. As to the concentration policy, EPA has in this notice announced a revised concentration policy that EPA believes is fully consistent with the requirements of the APA. This revised policy is not intended to be of controlling effect either on EPA or regulated parties. Rather, it is intended as guidance for EPA in administering its authority under FFDCA. For example, EPA has explained in some detail in its revised concentration policy what types of data it intends to place primary reliance upon in determining whether section 409 FARs are needed. However, EPA has noted its willingness to consider other information and arguments. Thus, because the revised concentration policy is not intended as a binding regulation, it need not be promulgated through notice and comment rulemaking.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests.

Dated: June 9, 1995.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 95-14683 Filed 6-12-95; 12:20 pm]

BILLING CODE 6560-50-F

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 2078]

Petition for Reconsideration of Actions in Rulemaking Proceedings

June 9, 1995.

Petition for reconsideration have been filed in the Commission rulemaking

proceedings listed in this Public Notice and published pursuant to 47 CFR Section 1.429(e). The full text of this document are available for viewing and copying in Room 239, 1919 M Street, NW., Washington, DC or may be purchased from the Commission's copy contractor ITS, Inc. (202) 857-3800. Opposition to this petition must be filed on or before June 29, 1995. See Section 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions has expired.

Subject: Price Cap Performance Review for Local Exchange Carriers. (CC Docket No. 94-1)

Number of Petitions Filed: 3.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 95-14510 Filed 6-13-95; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA-1054-DR]

Missouri; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Missouri (FEMA-1054-DR), dated June 2, 1995, and related determinations.

EFFECTIVE DATE: June 2, 1995.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3606.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated June 2, 1995, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*), as follows:

I have determined that the damage in certain areas of the State of Missouri, resulting from severe storms, hail, tornadoes and flooding on May 13, 1995, and continuing is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("the Stafford Act"). I, therefore, declare that such a major disaster exists in the State of Missouri.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as

you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance and Hazard Mitigation Assistance in the designated areas. Individual Assistance may be provided at a later date, if warranted. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation measures will be limited to 75 percent of the total eligible and reasonable costs.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date for this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Warren M. Pugh of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of Missouri to have been affected adversely by this declared major disaster:

Benton, Boone, Cole, Gasconade, Franklin, Jefferson, Johnson, Miller, St. Charles, St. Clair, Ste. Genevieve and St. Louis Counties. (Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

James L. Witt,

Director.

[FR Doc. 95-14542 Filed 6-13-95; 8:45 am]

BILLING CODE 6718-02-M

FEDERAL MEDIATION AND CONCILIATION SERVICE

Grants Program Review and Advisory Committee; Notice of Postponing Meeting

AGENCY: Federal Mediation and Conciliation Service.

ACTION: Notice of postponing meeting.

SUMMARY: The Federal Mediation and Conciliation Service announces the postponing of the Grants Program Review and Advisory Committee meeting. The meeting was originally scheduled for June 19, 1995 through June 23, 1995 in Washington, DC. The new meeting date for the Committee is to be announced.

FOR FURTHER INFORMATION CONTACT: Peter Regner, Grants Program Manager, Federal Mediation and Conciliation, 2100 K Street NW., Washington, DC 20427, (202) 606-8181.