ENVIRONMENTAL PROTECTION AGENCY

[OPP–300409; FRL–4991–9]

The Pesticide Coordination Policy; Response to Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Response to Petition.

SUMMARY: This notice completes EPA's response to a petition filed by the National Food Processors Association and others in 1992 and additionally responds to a second petition filed by the same parties in 1995. The 1992 petition sought the repeal or revision of several EPA policies and interpretations related to how EPA coordinates actions under its various statutory authorities over pesticide residues in food. EPA has decided not to alter significantly its general policy of taking all applicable legal authorities into account in ruling on a pesticide use. The 1995 petition urged EPA to rapidly complete its response to the 1992 petition. By publishing this notice EPA has met that request.

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SUPPLEMENTARY INFORMATION:

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 (FFDCA) was not subject to an exception for pesticide uses which pose a *de minimis* cancer risk. Prior to the decision becoming final, in September 1992, 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. EPA issued a partial response to the petition on June 14, 1995 (60 FR 31300) (June 1995 NFPA Response), and this notice completes EPA's response. Following the June 1995 NFPA Response, the same food processors and growers filed a second petition urging a prompt response to the entirety of its 1992 petition and raising various other issues. This second petition is addressed in this document as well.

II. Background

A. Statutory Background

Pesticide residues in human and animal food in the United States are regulated under provisions of the 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 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 affects 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. Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration (FDA) and the U.S. 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. Coordination of the Statutory Provisions Governing Pesticides

EPA regulations in 40 CFR 152.112(g) specify that FIFRA registrations for food-use pesticides will not be approved until all necessary tolerances and food additive tolerances have been obtained. As a policy matter, EPA has taken a similar approach to FFDCA sections 408 and 409, not granting section 408

tolerances until needed section 409 FARs have been granted.

EPA describes this linkage of its statutory authorities 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.

Inextricably related to the coordination policy is EPA's concentration policy. The concentration policy establishes the criteria as to when approval is needed for food-use pesticides under FFDCA section 409, and hence the Delaney clause. Prior to the June 1995 NFPA Response, EPA used a ''concentration in fact'' standard as the test of whether a use needs a section 409 FAR. The concentration in fact standard was met and a FAR deemed necessary 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. In its June 1995 NFPA Response, EPA modified its concentration policy by recognizing that: (1) Data and information other than processing studies are relevant to the question of whether a section 409 FAR is needed to prevent the adulteration of processed food, and (2) the ready-to-eat criterion in the flow-through proviso had to be considered in making determinations as to the need for section 409 FARs.

III. The NFPA Petitions

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 FFDCA. (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. With respect to the coordination policy, the NFPA petition argues that the coordination policy is 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 when, under the *Les* decision, the associated section 409 FARs have to be revoked (or cannot be established).

EPA sought public comment on the petition (58 FR 7470; February 5, 1993). Extensive public comment was received and significant comments are discussed in this notice. Following the June 1995 NFPA Response, the main issue in the NFPA petition that remains to be addressed is the coordination policy.

On July 10, 1995, NFPA filed a second petition (NFPA Petition II). This petition sought a quick decision on the coordination policy and raised two additional issues. First, the petition reiterated arguments made by NFPA in comments filed on its original petition that pesticide residues in processed food exceeding the applicable section 408 tolerance fall under section 406 of the FFDCA and not section 409. Second, NFPA asked that EPA rapidly implement the revised policies in the June 1995 NFPA Response and contended that the FFDCA barred EPA from revoking any FARs on Delaney clause grounds prior to reexamining the need for the FARs under the revised concentration policy.

IV. Summary of EPA Response to NFPA Petition

Unit V. of this document sets forth EPA's response to the NFPA petition regarding EPA's coordination policy. EPA has decided to retain its coordination policy largely intact. EPA believes that it has a fundamental responsibility to avoid inconsistent action under its statutory authorities and that this responsibility is best met by its coordination policy. Legally-used pesticides should not result in illegal food. However, EPA is willing to consider an exception to a coordination approach to avert severe economic disruption if other steps are feasible to prevent adulterated processed food from entering commerce. EPA rejects NFPA's argument that any needed tolerances for pesticide residues in processed food should be set under section 406 rather than section 409.

By publishing this notice, EPA has met the central request of NFPA Petition II—that EPA make a decision regarding the coordination policy. This notice also responds to the other issues in that petition. As noted above, EPA rejects the contention that pesticide residues in processed food should be regulated under section 406. Additionally, in Unit VI. of this document EPA explains that as a policy matter it intends to examine whether, for tolerances for which a proposed revocation on Delaney clause grounds is pending, revocation on the basis of its revised concentration policy is appropriate. However, EPA also makes clear that it disagrees with NFPA's suggestion that such a course is required by the statute.

V. Coordination of Authorities under FIFRA and FFDCA

A. Coordination Policy

EPA's coordination policy represents EPA's attempt to apply its various statutory mandates on pesticides in a consistent fashion. It is based on the rationale that actions approved under one statute or one provision of one statute should not lead to illegal consequences under another provision. Simply put, if farmers use a pesticide lawfully on their crops, the food made from those crops should not be rendered illegal because of the presence of pesticide residues. The coordination policy predates the existence of EPA and can be traced back at least to 1963 when Congress recognized that USDA and FDA coordinated their actions under FIFRA and FFDCA, respectively. S. Rep. No. 573, 88th Cong., 1st Sess. 2-3, 9-10 (1963). In fact, the drafters of section 408 actually suggested that government action on pesticides under FIFRA and FFDCA should be coordinated. S. Rep. 1635, 83rd Cong., 2d Sess. 3 (1954). Congress, however, has never codified this policy except to the limited extent it has required that tolerances be in place before states may grant special local need registrations under FIFRA. 7 U.S.C. 136v(c)(3).

EPA has continued the FDA and USDA practice of coordinating its action under FIFRA and the FFDCA. By regulation, EPA has made it a requirement of FIFRA registration that all ''needed'' tolerances under sections 408 and 409 be in place. 40 CFR 152.112(g); *see* 40 CFR 162.7(d)(3)(v) (1976) (the predecessor to the current regulation). Although not included in any regulation, EPA has generally followed a policy of not granting a section 408 tolerance if a section 409 FAR is needed but has not been or cannot be approved. 53 FR 41104, 41108 (October 19, 1988). EPA believes a necessary corollary to this policy and regulation is that if a needed tolerance is revoked, all corresponding tolerances and the registration should be removed as well.

The original NFPA petition, as well as many of the comments on the petition, blurs the distinction between the existence of the coordination policy and

the criteria EPA follows in determining when a food additive tolerance is ''needed.'' The criteria for when a food additive regulation is needed are what EPA describes as its concentration policy. In the June 1995 NFPA Response, EPA has addressed the concerns expressed regarding its concentration policy.

The main criticism of the coordination policy by the NFPA petition is that through this policy EPA has ''imported'' the Delaney clause into section 408 and FIFRA. EPA, the petition asserts, has illegally ignored the risk/benefit standard in FIFRA as well as section 408's requirement that EPA set tolerances so as to ''protect the public health'' taking into consideration the ''necessity for the production of an adequate, wholesome, and economical food supply.'' However, NFPA did acknowledge that ''[u]nder some circumstances revocation of a 409 FAR may appropriately prompt reexamination of the basis for the counterpart section 408 tolerance, in order to determine whether the raw product tolerance remains consistent with the statutory criteria prescribed in section *408*.'' (Comments of the NFPA at 9 n.4)(emphasis in original).

A second legal objection to the coordination policy raised by the NFPA petition is that choosing a coordination policy approach over a policy approach which focuses on enforcement ''stands the flow-through provision on its head.'' (NFPA Petition at 35). According to NFPA, ''[t]he EPA policy *prohibits* any use of a pesticide on a crop if the Delaney clause precludes issuance of a section 409 food additive regulation for the pesticide in the processed food, regardless of whether processors can in fact satisfy the conditions of the proviso.'' *Id.* at 36 (emphasis in original). Finally, the NFPA petition argues that the coordination policy is inconsistent with FDA's contemporaneous interpretation of the statute.

Taking a different view, the Natural Resources Defense Council (NRDC), in comments on the NFPA petition, contends that the FFDCA mandates that EPA follow a coordination policy. Noting that section 408 requires consideration of the ''necessity for a wholesome food supply'' and ''other ways in which the consumer may be affected by the same pesticide chemical,'' NRDC argues that for a pesticide which concentrates above the section 408 level, these requirements bar establishment of a tolerance. (Comments of NRDC at 11-12). NRDC states that a use of a pesticide which produces adulterated processed food does not contribute to a ''wholesome'' food supply and that EPA is required to consider that the pesticide produces adulterated food by the ''other ways in which the consumer may be affected'' clause.

1. *The proper relationship of the Delaney clause to FIFRA and FFDCA section 408.* EPA agrees with NFPA that the Delaney clause is not a legal standard directly governing section 408 tolerances or FIFRA registrations. *See Environmental Defense Fund v. HEW*, 428 F.2d 1083, 1091 (D.C. Cir. 1970). Nonetheless, EPA believes that in some circumstances the Delaney clause affects decisionmaking under FIFRA and FFDCA section 408. EPA has an obligation to attempt to construe its statutory authorities governing the same matters as harmoniously as possible. EPA has construed FIFRA and FFDCA sections 408 and 409 to be overlapping in some respects, and EPA believes it is appropriate, where an overlap is identified, to give some weight to all aspects of the statute, including the Delaney clause.

There is an overlap between FIFRA and FFDCA sections 408 and 409 where approval of a pesticide use on raw food under FIFRA or FFDCA section 408 can lead to residues in processed food which exceed the section 408 tolerance. This overlap occurs because EPA takes into account the exposure which results from pesticide residue carryover to processed food from application to the raw food in considering registrations under FIFRA and section 408 tolerances for food-use pesticides. Thus, the computer model EPA uses for dietary risk assessment takes into account potential residues in all forms of foods, not just the actual raw crop to which the pesticide is applied. EPA believes considering pesticide exposure from all food to be an essential part of its basic statutory responsibility under FIFRA and section 408 to evaluate the risk posed by the specific pesticide use in question. Given the broad statutory standards in FIFRA (''unreasonable risk'') and FFDCA section 408 (''protect the public health''), it would be difficult to describe consideration of all possible residues as not in accordance with law or arbitrary or capricious.

Having identified an overlap, the question remains as to how the various provisions are to be construed harmoniously. EPA believes this is best accomplished by treating the Delaney clause as indicating that Congress had a heightened concern for carcinogenic pesticide residues in processed food where those residues exceed the section 408 tolerance. Thus, EPA, in making the risk/benefit balancing determination called for under FIFRA and section 408 for a carcinogenic pesticide, takes into account the likelihood that residues of the pesticide will exceed the section 408 tolerance in processed food and the added weight such overtolerance residues are due in light of the Delaney clause.

Additionally, in evaluating the benefits provided by use of a pesticide in the FIFRA and section 408 risk/benefit decision, EPA must consider the extent to which use of a pesticide could result in adulterated food. Adulterated food resulting from use of a pesticide would decrease any benefits the pesticide provided to society. Thus, the Delaney clause's effect of denying a FAR for carcinogenic pesticides affects benefits determinations as well as risk evaluations under FIFRA and section 408.

Thus, EPA's coordination policy does not depend on writing the Delaney clause into FIFRA and FFDCA section 408 but is based on interpretation of the legal standards of FIFRA and section 408 and a consideration of the full range of residues that may result from use of a pesticide consistent with approval under FIFRA and section 408.

Under EPA's formulation of how the Delaney clause is appropriately considered in FIFRA and section 408 actions, there still remains a degree of agency flexibility. In situations at the extremes, either where there is evidence showing that residues in processed food would always exceed the section 408 tolerance or that such overtolerance residues would never occur, EPA will have little or no discretion. For example, where the possibility of residues exceeding the section 408 tolerance depends upon misuse of the pesticide (and such misuse would generally not be expected), EPA believes its authority to revoke the section 408 tolerance associated with such a use and cancel its FIFRA registration would be limited. The opposite of course is true as well: if data show that processed food will always contain residues at levels greater than the section 408 tolerance level and that the raw crop is commonly processed, EPA would have little discretion over whether to establish or continue the FIFRA use and FFDCA section 408 tolerance. In circumstances between these two extremes EPA has more flexibility. For example, where legal use patterns and normal circumstances suggest a possibility of overtolerance residues in more than a trivial amount of processed food but the probability of overtolerance residues is low, EPA has two options.

One option, advocated by NFPA, would be not to establish a food

additive regulation, but leave the section 408 tolerance in place and rely on enforcement actions under the statutory scheme as laid out in the flow-through provision to police the food supply. The second option would be to follow a coordination policy such as EPA's present one which would call for a revocation of the section 408 tolerance and cancellation of the FIFRA registration. Selecting between the two requires balancing of a number of factors including resource constraints, public health considerations, industry concerns regarding both flexibility and certainty, agency credibility, effects on the price and availability of food for consumers, and impacts upon agriculture. NRDC's legal arguments do not convince EPA that there is no room for policy judgment in this area. NRDC's arguments appear to rely on the premise that all processed food produced from a particular crop would have pesticide residues in excess of the section 408 tolerance.

EPA believes that several policy factors weigh in favor of its coordination policy. First, FDA has limited resources for policing the food supply. The difference in resource requirements between charging FDA with finding adulterated food already in the food distribution system and requiring EPA to make a pre-marketing judgment are enormous. A pre-marketing judgment can be made on a discrete data set but after-the-fact policing of the food supply involves sampling of food throughout the country. The NFPA in instituting its Protective Screen Program against illegal residues has recognized the limitations of relying on after-the-fact monitoring. The NFPA's Protective Screen Program states that:

> It is important to recognize that monitoring or testing programs cannot serve as the sole or even primary assurance that finished food products will be free from illegal pesticide residues. The emphasis must be on preventing the occurrence of contamination rather than reliance on its detection after-the-fact. (NFPA Petition, App. B at 6).

Second, if EPA places primary emphasis on an after-the-fact monitoring scheme and thus FDA increasingly must seize adulterated food, the public may become unduly alarmed and as a consequence avoid foods which are critical to a healthy, well-balanced diet.

Third, NFPA has not adequately explained how an after-the-fact monitoring scheme could be enforced other than through a massive expansion of FDA's sampling program. In fact, the NFPA itself acknowledges that it relies on EPA's coordination policy (legal use should result in legal food) as its guiding premise in preventing adulteration of food. The NFPA Protective Screen Program provides:

> The premise of the NFPA Protective Screen Program is that if a pesticide is used legally to produce a raw agricultural commodity, then the resulting residue on the pesticide in the food will be legal. Thus, the emphasis of the program is on the prevention of illegal pesticide uses and residues, as opposed to detection after the fact. (NFPA Petition, App. B at 1).

Finally, EPA must take into account, as noted in comments by NRDC, that the history of the FFDCA indicates a congressional preference in favor of pre-market clearance of potentially deleterious substances rather than a dependance on after-the-fact seizure of adulterated food. *See Ewig Bros.*, 502 F.2d at 720-21.

It is more difficult to weigh the risk considerations relative to removing specific pesticide uses from the market under the coordination policy. Independent of statutory constraints, EPA's judgment is that many uses that would have to be revoked under the coordination policy pose insignificant risks. If the risks from these uses were significant, EPA would likely be taking action under FIFRA or FFDCA section 408. On the other hand, EPA cannot ignore that such uses result in levels of residues in processed food that Congress has concluded, through passage of the Delaney clause, should not be allowed.

EPA has also considered the potential impacts on agriculture that could occur from the loss of pesticide uses that a coordination approach might cause. The Economic Impact Analysis prepared by EPA shows that, if the concentration and coordination policies were left intact, there could be substantial impacts upon agriculture. The changes EPA has made in its concentration and ready-to-eat policies in the June 1995 NFPA response are expected to greatly diminish the number of section 409 tolerances required and thus the number of uses affected. In applying those policies to a proposed revocation of animal feed tolerances published in the Federal Register of September 21, 1995 (60 FR 49142), EPA concludes that almost half of the 36 FARs that were potentially inconsistent with the Delaney clause can be revoked as unnecessary under EPA's revised concentration policy. Moreover, if individual uses are affected, EPA believes that the impacts on consumers and agriculture will be minimal. As a general matter, therefore, EPA concludes that the various policy factors weigh strongly in favor of following a coordination policy.

EPA would emphasize that its choice of a coordination approach is a policy judgment and although, as a general matter, EPA intends to adhere to this approach, EPA cannot rule out the possibility that in a given situation the balance of factors supporting a coordination policy may shift away from a pre-market clearance procedure and toward the more costly and inefficient process of after-the-fact enforcement. For example, application of the coordination policy may result in the cancellation of a use or group of uses that is so central to the production of a certain crop that the revocation of that use or uses would severely disrupt domestic production of that commodity with attendant consequences to the price and availability of food to the consumer. In these circumstances, EPA believes it may be appropriate to allow an exception to the coordination policy.

EPA believes, however, that the potential for excepting a pesticide use from the coordination policy is slight. EPA would only do so where a clear showing of severe economic disruption was made and that economic disruption outweighs EPA concerns regarding an after-the-fact monitoring scheme both generally and as to the specific commodity involved. One critical factor here may be the ability of growers and processors to provide information demonstrating how an after-the-fact monitoring program could feasibly be implemented.

2. *Alleged inconsistency with the flow-through provision*. A second legal objection to the coordination policy raised by the NFPA petition is that choosing a coordination policy approach over one which focuses on enforcement ''stands the flow-through provision on its head.'' (NFPA Petition at 35). According to NFPA, ''[t]he EPA policy *prohibits* any use of a pesticide on a crop if the Delaney clause precludes issuance of a section 409 FAR for the pesticide in the processed food, regardless of whether processors can in fact satisfy the conditions of the proviso.'' *Id.* at 36 (emphasis in original).

When presented in this manner, NFPA's claim is overstated. The coordination policy is based on the rationale that data show that processing of legally-treated crops under good manufacturing practices may produce adulterated food. If the NFPA is concerned that EPA has failed to consider whether food processors can reduce residues in processed food below the section 408 tolerance, this is not a quarrel with the coordination policy so much as with the EPA criteria as to when a section 409 FAR is needed. EPA believes the adjustments to its concentration policy in the June 1995

NFPA Response respond to NFPA's concerns on this issue.

Ultimately, however, there remains the basic disagreement between EPA and the views presented by NFPA in its petition. EPA believes that it has an important role to play at the pre-market stage of pesticide regulation to ensure that legally-treated crops produce legal food. NFPA argues that pre-market regulation by EPA is unnecessary—growers and processors are capable of insuring that residues in processed food do not exceed the section 408 tolerance. NFPA, however, presents no scheme for enforcing such a system. In fact, as noted above, NFPA itself has admitted that generally an enforcement scheme premised solely on after-the-fact monitoring cannot work.

3. *Contemporaneous interpretation.* A third legal objection to the coordination policy raised by NFPA is that it departs from FDA's interpretation of the relationship of sections 408 and 409 issued contemporaneously with the passage of section 409. NFPA claims that FDA in initially implementing section 409 did not follow a policy of requiring that a section 409 FAR for a pesticide be established where there was a possibility that residues of the pesticide in processed food could exceed the RAC tolerance. NFPA cites no explicit statement of FDA policy to support this claim; instead, NFPA relies solely on inferences drawn from an FDA regulation and FDA's purported failure to require food additive regulations in situations where a coordination policy allegedly would have dictated they be established.

The FDA regulation cited by NFPA contains an explanation of the flow-through provision. NFPA places particular emphasis on the following example included in the regulation:

> If fruit bearing a residue of 7 parts per million of DDT, permitted on the raw agricultural commodity is dried and a residue in excess of 7 parts per million of DDT results on the dried fruit, the dehydrated fruit is adulterated unless the higher tolerance for DDT is authorized by the regulations in this part. 21 CFR 170.19 (originally adopted 24 FR 2434, March 29, 1959).

According to NFPA, this rather straightforward explication of the flow-through provision proves FDA did not require food additive regulations where concentration in the processed food was a possibility because, if it had, the situation described in the regulation (processed food having residues above the RAC tolerance and no section 409 FAR in place) could never occur. If the situation could never occur, NFPA's logic runs, FDA would not have used it as an example in its regulations.

EPA, however, does not believe the FDA example is inconsistent with a coordination policy approach. FDA's regulation is designed to explain the operation of the flow-through provision. It is difficult to see how FDA could adequately explain that provision without using an example similar to the one chosen. Moreover, a mere explanation of how statutory language operates to render certain food adulterated does not preclude the existence of a policy designed to prevent such adulteration from occurring. The example remains relevant even if a coordination policy is in place. EPA's coordination policy does not guarantee that residues in processed food will never exceed the section 408 tolerance. Rather, EPA attempts to identify at the pre-marketing stage, pesticide uses which may result in residues in processed food greater than the section 408 tolerance. In actual practice, EPA's premarketing judgment may be incorrect and overtolerance residues may occur in processed food. FDA's dried fruit example is consistent with its responsibility to identify the consequences of residues over the section 408 tolerance in processed food despite whatever policies FDA followed to avoid that situation in the first place.

NFPA's reliance on the nonexistence of certain food additive regulations for various registered pesticide uses is an equally weak basis for NFPA's claim that FDA's contemporaneous construction rejected a coordination approach to sections 408 and 409. NFPA claims FDA could not have followed a coordination policy because FDA issued numerous RAC tolerances on foods without establishing food additive regulations despite the fact that these foods (e.g., tomatoes) have processed forms (e.g., tomato paste) in which residues possibly could concentrate.

However, NFPA fails to mention that FDA was setting section 409 FARs for some processed foods as early as 1960 out of concern over concentrating residues. See 25 FR 2076 (March 11, 1960); 25 FR 10570 (November 4, 1960); 27 FR 3694 (April 16, 1963). This is consistent with EPA's current practice of requiring section 409 FARs only where data on a specific pesticide use show that residues concentrate when a RAC is processed and thus there may be residues over the section 408 tolerance in the processed food. EPA has not, for example, set section 409 FARs on tomato paste for every pesticide that is registered on tomatoes. Accordingly, the fact that FDA did not set food additive regulations on every processed food in which residues could possibly concentrate indicates little.

4. *Segregation of crops.* One other significant issue raised in comments on the NFPA petition relating to EPA's coordination policy was the argument that a coordination policy was not justified because farmers could segregate crops between the fresh and processed markets. EPA believes that this argument is a valid criticism of the coordination policy only if it could be shown that segregation is generally possible across the entire agriculture industry. If not, claims that a specific crop can be segregated relate solely to the wisdom of applying the coordination policy in a particular instance rather than to the rationale for the underlying coordination policy. EPA believes that whether segregation can occur for a specific crop is an issue best examined on a case-by-case basis.

EPA believes that the comments it received in response to the NFPA petition demonstrate that segregation of crops for fresh markets is not generally possible. Those commenters most aggressively asserting that segregation was possible did not represent agricultural interests but chemical companies. Even among chemical companies, such as the National Agricultural Chemicals Association, however, there was recognition that market separation was not always a possibility. Comments from growers, for the most part, support EPA's own experience that in many instances farmers do not and cannot know in which market a crop will eventually be sold. Although some growers representing certain crops in specific regions of the country claim in their comments that market segregation is possible in their unique circumstances, comments from other growers emphasize that a decision about marketing is a product of factors beyond their control. Comments to this effect were received from the North Carolina Farm Bureau, the California Tree and Grape Association, Sun-Diamond Co., and an apple processor. Several commenters, while noting the general difficulty of market segregation and thus their general approval of the coordination policy, suggested that EPA should grant exceptions to the policy where the circumstances show segregation possible (State of California, Virginia Agriculture Department, Florida Agriculture Department, Farmer Cooperative).

As noted in the June 1995 NFPA Response, EPA will consider whether crops can be segregated between the fresh and processed market on a case-

by-case basis in deciding whether a section 409 FAR is needed.

B. Regulation of Pesticides Under Section 406

In comments that NFPA provided in response to the notice published by EPA, NFPA retreated in its challenge to the coordination policy. Instead of arguing that coordination by the Agency of its various statutory authorities was illegal, NFPA asserts that EPA's real error had been in construing section 409 to cover pesticides in processed food. Pesticides in processed foods should be regulated under FFDCA section 406, NFPA argues, and it raises no objection to EPA requiring section 406 tolerances ''if there is a substantial likelihood that an appreciable quantity of concentrated processed food when ready to eat will contain residues significantly in excess of the raw product tolerance.'' (Comments of NFPA at 32).

Response to this comment first requires an explanation of section 406 in the FFDCA. Section 406 was enacted in 1938 and was the original provision in the FFDCA granting FDA tolerance-setting authority for pesticide residues in food. It provides that FDA may set tolerances for ''poisonous or deleterious substances added to food'' where such substances are required in the production of food. 21 U.S.C. 346. Section 406 was rendered obsolete for pesticides in raw agricultural commodities by the passage of section 408 in 1954. Congress in passing section 408, however, noted, in legislative history, that pesticides in processed foods were still to be governed under section 406. With the passage of the section 409 food additives provision in 1958, FDA, and, in turn, EPA, discerned a change in congressional intent and began to regulate pesticides in processed food under section 409. The principal basis for that interpretation was the fact that the flow-through provision of section 402, added in connection with section 409, exempted pesticide residues in processed food that were below the appropriate RAC tolerance from section 409. FDA and EPA reasoned that Congress would not have exempted such pesticide residues from section 409 unless they would have fallen within that provision in the absence of the exemption provided by section 402. That interpretation has been upheld. *United States v. Ewig Bros. Co., Inc*., 502 F.2d 715, 722 (7th Cir. 1974).

NFPA challenges that interpretation relying on two statutory bases. First, NFPA points to the definition of ''food additive'' which specifically exempts from the coverage of that term (1) ''a pesticide chemical in or on any raw agricultural commodity;'' and (2) pesticide chemicals . . . used in the production, storage, transportation of raw agricultural commodities.'' NFPA argues that if these two exclusions are not to be construed as redundant, the latter must extend to pesticides in foods other than RACs — i.e. pesticides in processed foods. Second, NFPA notes that the flow-through provision is drafted so as to exclude pesticide residues in processed foods below the RAC tolerance not only from section 409 but from section 406 as well. Thus, NFPA argues, the flow-through provision, rather than providing a clear signal that pesticides in processed foods are food additives, is ambiguous on this question.

The Ninth Circuit in *Les v. Reilly* wrote that ''the statute unambiguously provides that pesticides which concentrate in processed food are to be treated as food additives . . . .'' *Les v. Reilly*, 968 F.2d at 989. Similarly, the Seventh Circuit in *United States v. Ewig Bros. Co., Inc*. 502 F.2d at 723, decision found it ''clear'' that section 409 governed pesticide residues in processed food. Even EPA, in arguing in its Order adopting a *de minimis* exception that there was considerable confusion in Congress in 1958 regarding whether section 409 would apply to pesticides, noted that there is support for the interpretation that pesticides in processed foods are ''food additives.'' (February 25, 1991; 56 FR 7763) It must be noted, however, that neither the Ninth nor Seventh Circuits addressed the exclusion in the food additive definition for pesticides ''used'' in the production of RACs or the references in the flow-through provision to both sections 406 and 409. Nonetheless, at best, NFPA's argument demonstrates no more than a possible ambiguity as to whether Congress intended pesticides in processed foods to be regulated under section 406 or 409. *See* 57 FR 20841 (May 12, 1992) discussing ambiguity in the statute.

In circumstances where the ambiguity of the statute allows for more than one reasonable interpretation, the agency charged with the administration of the statute is entitled to considerable deference on its policy judgment as to which interpretation best furthers the goals of the statute. *Chevron v. NRDC*, 467 U.S. 837, 842-843 (1984). FDA's judgment when section 409 was enacted, as well as both FDA's and EPA's operating premise for the last 37 years, has been that regulating pesticides in processed food is best accomplished under section 409.

Adopting NFPA's section 406 approach would certainly be a step backward in the evolution of the FFDCA as an effective regulatory statute. Section 406 was Congress' first effort in conferring tolerance-setting authority. It had several weaknesses, one of which was that for covered substances such as pesticides, where FDA had not set a tolerance, FDA could only successfully remove a food containing pesticide residues from commerce by proving before a jury as a matter of fact that the food was injurious to health. This scheme was abandoned in sections 408 and 409 which make food containing a pesticide or food additive adulterated as a matter of law if there is no tolerance established for the pesticide or food additive. As the Seventh Circuit recognized, if EPA were to return pesticides in processed foods to the jurisdiction of section 406, it ''would result in the anomaly that a chemical such as DDT [for which there are no tolerances] would adulterate all raw fish, but adulteration of processed fish would be determined on an uncertain case-by-case basis.'' *Ewig Bros.*, 502 F.2d at 722.

Certainly, the different standards in sections 408 and 409 have made the statutory scheme difficult to administer, and the Delaney clause has the potential of removing some beneficial pesticide uses from the market even though these uses appear to pose negligible human cancer risks. By this policy statement, the June 1995 NFPA Response, and related actions, however, EPA will have clarified to a large extent how it will administer and coordinate action between sections 408 and 409, which should ease the administration of the provisions. Further, the potentially disruptive effect of the Delaney clause on agriculture is uncertain. Thus, even if NFPA is correct that Congress expressed no clear intent on what provision should govern pesticide residues in processed food and therefore EPA may regulate residues in processed food under either section 406 or 409, EPA declines to change from its current practice of regulating such residues under section 409 for the reasons stated above.

VI. The Relationship of Decisions Regarding the Need for Section 409 FARs and Delaney Clause Determinations

The NFPA Petition II requests that EPA implement its new concentration policy as soon as possible by initiating revocation proceedings for all section 409 FARs now deemed unnecessary. The petition asserts that such revocation proceedings are likely to be less

resource intensive than revocations based on the Delaney clause. Further, the petition claims that EPA is barred by the FFDCA from revoking a FAR under the Delaney clause or any other safety-related grounds prior to reevaluating under its revised concentration policy whether the FAR is necessary.

As a policy matter, EPA generally agrees that it makes sense to revoke FARs, where appropriate, as unnecessary rather than to litigate the difficult science questions involved in an induce cancer finding. For that reason, EPA has consistently revoked FARs that otherwise were barred by the Delaney clause on lack of need grounds where it was clear that such grounds supported revocation. (See mancozeb on raisins, June 30, 1994; 59 FR 33694, and trifluralin on mint, July 28, 1995; 60 FR 38781.) However, EPA strongly disagrees with NFPA's suggestion that the statute has established a hierarchy of grounds for the revocation of FARs that subordinates the public health concerns embodied in the safety standard in section 409 to a determination of whether residues above the section 408 tolerance are expected. After reviewing the legal arguments put forward by NFPA, EPA concludes they are without basis.

NFPA's argument is as follows:

> As a matter of law, EPA is precluded from applying the Delaney clause to pesticides that come within the provisions of the flow-through proviso in section 402(a)(2). That proviso flatly prohibits EPA from determining that an agricultural pesticide in a processed food is ''unsafe,'' notwithstanding the provisions of section 409, if the residue has been removed to the extent possible in good manufacturing practice and the concentration of the residue in the processed food when ready to eat is not greater than the raw commodity tolerance. Yet, if EPA were to revoke a section 409 tolerance because the pesticide is found to induce cancer within the meaning of the Delaney clause, the statutory basis of that action would necessarily be that the pesticide is ''unsafe'' under the terms of section 409 and section 402(a)(2)(C). NFPA Petition II at 3 (footnote omitted).

EPA agrees with NFPA that EPA cannot declare a pesticide residue that complies with the flow-through provision ''unsafe'' as that term is used in section 402(a)(2)(C). However, EPA disagrees that revoking a section 409 FAR on safety grounds could have the effect of rendering residues in compliance with the flow-through provision ''unsafe'' under section 402(a)(2)(C). Revocation of a FAR for whatever reason can only affect residues in food exceeding the section 408 tolerance. Residues in processed food below the section 408 tolerance are, by order of the flow-through provision, not ''unsafe'' within the meaning of section 409. EPA's conclusion, in revoking a FAR, that residues exceeding the section 408 tolerance do not meet the safety standard in section 409(c) is not meant to, and, for that matter, cannot change the operation of the flow-through provision as to residues below the section 408 tolerance.

NFPA's argument is based on two fundamental misreadings of the statute. First, NFPA apparently misunderstands the relationship between section 409 FARs and section 402(a)(2)(C) including the flow-through provision. NFPA appears to believe that revocation of a section 409 FAR somehow affects residues governed by the flow-through provision. Second, NFPA wrongly treats as comparable the ''unsafe'' determination under section 402(a)(2)(C) and the safety finding required in section 409(c) regarding the establishment or revocation of FARs. A correct reading of the statute on either of these two points shows the flaw in NFPA's argument. Below, EPA has set out in detail an explanation of the proper interpretation of the interrelationship between section 402 and section 409.

FARs for food additives, including pesticide residues in processed food, are established under section 409. Section 402(a)(2)(C) makes these FARs enforceable by defining the circumstances under which a food containing a food additive is adulterated.

The key to the operation of sections 402(a)(2)(C) and 409 is the statutory phrase ''unsafe within the meaning of section 409.'' Section 402(a)(2)(C) declares that a food containing a food additive is adulterated if the food additive is ''unsafe within the meaning of section 409.'' Subsection (a) of section 409 reciprocates this crossreference from section 402(a)(2)(C) by stating:

> [a] food additive shall . . . be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 402(a), unless . . . there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section . . . . 21 U.S.C. 348(a).

Thus, section 409(a) defines ''unsafe within the meaning of section 409'' by means of a mechanical *per se* rule — a food additive is ''unsafe'' and renders food adulterated unless the additive is in compliance with a FAR and, where no FAR exists, a food additive is necessarily unsafe. The preeminence of a FAR in adjudicating whether a food additive is ''unsafe'' under section 402(a)(2)(C) is confirmed by the closing sentence of section 409(a) which forbids enforcement action against a food additive under a substantive safety standard (''injurious to health'') if a FAR has been established.

Unlike the adulteration determination under section 402(a)(2)(C), the process for establishing, modifying, and revoking FARs does involve substantive safety determinations. Subsection (c) of section 409 states FARs shall not be promulgated unless ''use of the food additive, under the conditions of use to be specified in the regulation, will be safe . . . .'' Subsection (c) then lists numerous factors to be considered in making this substantive safety determination. 21 U.S.C. 348(c)(5).

The final wrinkle in the section 402/409 scheme is the flow-through provision in section 402(a)(2)(C). The flow-through provision places an important limitation on the application of the *per se* ''unsafe'' rule of section 409(a) in situations where no FAR has been established for a pesticide residue in a processed food. The flow-through provision specifies that pesticide residues in processed foods are not deemed unsafe within the meaning of section 409 where, among other things, such residues are in conformity with the section 408 tolerance established for the precursor raw agricultural commodity. Thus, section 402(a)(2)(C) creates, in essence, two regulatory zones for any particular pesticide in food. The first zone covers the range of residues from zero up to the section 408 tolerance. The second zone applies to all levels of residue exceeding the section 408 tolerance. In the first zone, pesticide residues are statutorily removed from section 409(a)'s *per se* ''unsafe'' rule. In the second zone, residues are *per se* ''unsafe'' and render food adulterated as a matter of law (i.e. no particularized safety finding required) unless EPA has established a FAR finding such level of residues to be substantively ''safe'' under section 409(c). Such FARS permitting residues in zone two apply, in effect, only to residues in zone two because if a FAR is revoked, residues in zone one would once again enjoy the protection of the flow-through provision.

Thus, it is clear that the revocation of a FAR under the section 409(c) safety standard only affects residues in processed food above the section 408 tolerance (zone two residues) and not residues within the flow-through provision (zone one residues). This is true even where residues of a pesticide in processed food do not exceed the section 408 tolerance. Whether or not residues in fact exceed the section 408 tolerance, the presence of a section 409

FAR legalizes such residues and revocation of the FAR can do nothing more than remove the allowance for such overtolerance residues. NFPA has offered no explanation for how the factual circumstances surrounding the residue levels of a certain pesticide could serve to rewrite the statutory provisions governing the legal effect of the revocation of a FAR.

Further, it is also clear that the safety finding under section 409(c) is entirely distinct from the ''unsafe'' determination under section 402(a)(2)(C). Section 409(c) involves a substantive safety evaluation, section 402(a)(2)(C) is a mechanical test for adulteration which involves nothing more than evaluating compliance with a FAR. Although a lack of safety finding under section 409(c) has an effect on how the mechanical ''unsafe'' test under section 402(a)(2)(C) will operate as to residues in zone two (once a FAR is revoked residues in zone two become ''unsafe'' as a matter of law), such a finding would have absolutely no legal effect on residues in zone one. Thus, NFPA is wrong to treat the lack of safety finding under section 409(c) as equivalent to a section 402(a)(2)(C) ''unsafe'' determination.

Unwittingly, NFPA's attempt to blur the distinction between the determinations in the FAR-setting process and the FAR enforcement process threatens to undermine Congress' carefully constructed scheme for the regulation of food additives and several other substances (pesticides in raw foods, new animal drugs, and color additives) which are regulated under the FFDCA under an identical scheme. As it now stands, section 402(a)(2) imposes a straightforward test: a pesticide, food additive, new animal drug, or color additive renders a food adulterated unless the present of the substance is consistent with a tolerance or use regulation promulgated under the applicable section of the FFDCA. If, however, the ''unsafe'' determination under section 402(a)(2)(C) has a substantive safety component, as advocated by NFPA, FFDCA tolerance or use regulations potentially lose their status as the ultimate arbiter over whether a food is adulterated. The consequence would be that proof that a food containing pesticide residues not in compliance with a FAR would not necessarily suffice to justify seizure of the food by FDA; nor would a showing that residues of a pesticide in food are within the FAR necessarily protect the food from a finding of adulteration. This lack of clarity concerning the legality of the residues of pesticides, food additives, new animal drugs, and color additives serves neither the public nor the regulated community. For this reason alone, NFPA's argument would have to be rejected.

In sum, NFPA's argument that EPA is legally barred from revoking a FAR on safety grounds prior to revisiting the need for the FAR has no basis in the statute. The premise of NFPA's argument — that the revocation of a FAR on safety grounds somehow automatically overrides the flow-through provision — is conceptually flawed. EPA has never claimed that its administrative determinations under section 409(c) disable the statutory command in the flow-through provision and NFPA has supplied no reasonable argument as to why such EPA determinations should have such effect. If a section 409 FAR is revoked on safety grounds, EPA will have to evaluate whether the corresponding section 408 tolerance, and the protection it provides to certain residues in processed food, should remain in place. However, the determination on the section 408 tolerance, as explained in Unit V. of this document, will turn on the safety standard in section 408 and not automatically follow from any safety finding under section 409(c).

VII. Potential Impacts on Agriculture Related to EPA's Coordination and Concentration Policies

In connection with its response to the NFPA petition, EPA conducted an Economic Impact Assessment as to potential impacts on agricultural producers as a result of continuation of EPA's existing policies without change. The assessment concluded that the total economic impact on affected producers could be as high as $500 million. The assessment concluded that some potentially significant impacts could occur on a small number of crops, but only three crops are estimated to incur impacts greater than 5 percent of their annual 1989-91 U.S. production value (pineapple 29%, sugarcane 13%, and grapes 5.1%). Absolute projected impacts were highest for sugarcane, grapes, potatoes, rice, and apples, which together comprised about 70 percent of total impacts projected.

For various reasons, however, the assessment presents a worst-case scenario and actual impacts are expected to be far less. The assessment did not take into account the changes in EPA's coordination and concentration policies adopted in this document and the June 1995 NFPA Response; rather, it assumed that all pesticide uses identified as potentially affected by the Delaney clause and EPA's coordination policy would be cancelled. As the recent proposed revocation of animal feed regulations (September 15, 1995; 60 FR 49142) illustrates, these revised policies have already reduced the number of uses potentially affected. Nor did the assessment consider other factors expected to mitigate impacts: (1) Only currently registered alternatives were assumed to be available for substitution, whereas FIFRA sec. 18 exemptions and section 24(c) registrations for alternative pesticides could avert significant impacts; (2) any cancellations of uses are likely to be phased in over several years rather than immediately and simultaneously.

Until new policy definitions and parameters are fully implemented, the extent of impact mitigation due to recent policy modifications cannot be predicted but the decrease in potential impacts is expected to be significant. EPA will update its Economic Impact Analysis when it evaluates remaining uses potentially affected by the Delaney clause.

VIII. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), it has been determined that this policy statement is a ''significant regulatory action'' because this action may raise novel policy issues arising out of legal mandates. As such, this action was submitted to the Office of Management and Budget for review and any comments or changes have been documented in the public record. This action reaffirms existing policy and has no direct adverse impacts on any entity, including small entities. I therefore certify that this policy statement does not require a separate Impact Analysis under the Regulatory Flexibility Act.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 19, 1996.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

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