ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 186

[OPP–300397; FRL–4977–3]

RIN 2070–AC18

Pesticides; Feed Additive Regulation Revocations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA has made determinations regarding 36 feed additive regulations (FARs) for 16 pesticides in animal feeds that were previously reported as potentially inconsistent with the Delaney clause in section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA). EPA is proposing to revoke 34 animal feed FARs because they are not needed to prevent adulterated food, and two additional animal feed FARs because they violate the Delaney clause.

DATES: Written comments, identified by the document control number [OPP-300397], must be received on or before December 19, 1995.

ADDRESSES: By mail, submit comments to: Public Response Section, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: OPP Docket, Public Information Branch, Field Operations Division, Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The telephone number for the OPP docket is (703)-305-5805. Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (or CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2 and in section 10 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). For questions related to disclosure of materials, contact the OPP Docket at the telephone number given above. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in the OPP Docket, Rm. 1132, at the Virginia address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP-300397]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Niloufar Nazmi, Special Review and Reregistration Division (7508W), Environmental Protection Agency, 401 M St., SW., Washington, DC, 20460. Office location and telephone number: Crystal Station #1, 2800 Crystal Drive, Arlington, VA. Telephone: 703-308-8010; e-mail: nazmi.niloufar@epamail.epa.gov.

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I. Introduction

In this document, EPA examines whether 36 FARs for 16 pesticides in animal feeds should be revoked, either because the FAR is inconsistent with the Delaney clause in section 409(c)(3) of the FFDCA or because the FAR is not needed to prevent adulterated feed under current Agency policies and guidelines. For those FARs which EPA determines should be revoked, EPA is in this document proposing revocation.

EPA concludes that the Delaney clause affects few of the FARS involved in this document, primarily because of revised Agency policies and guidelines governing when FARs are required to prevent adulterated animal feed. Although a combination of factors are responsible for this result, perhaps the most significant point is that the FARs in this document involve animal feeds. For example, almost half of the 36 FARs were judged unnecessary because EPA concluded that the animal feeds in question were not a significant portion of the livestock diet.

EPA will in the near future be making decisions concerning the fate of a number of FARs for processed human foods. EPA proposals are pending to revoke human food FARs for 11 pesticides covering 32 uses. The policies announced in the Agency's June 14, 1995 response to the National Food Processors' Association (NFPA) petition have been instituted, and EPA has begun to review the effects of those policies on its earlier proposals. EPA has not completed this analysis and so its results are uncertain, but the Agency believes that the effects of its policy changes will not be as dramatic for human, as opposed to animal, foods. For example, in general EPA has concluded that most processing byproducts used as animal feeds are not ready to eat; processed human foods are not as obviously amenable to such a broadly drawn conclusion. EPA anticipates that case-by-case determinations will be the rule for human foods.

Finally, EPA notes that the identification of pesticides and uses that are potentially subject to the Delaney clause is an ongoing process as EPA receives new cancer and processing studies required as part of reregistration. When EPA concludes that a processed food or feed tolerance is necessary under FFDCA section 409 for a pesticide that induces cancer within the meaning of the Delaney clause, EPA will take action to revoke or deny that tolerance.

II. Background

A. Statutory Background

The Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 301 et seq.) authorizes the establishment of maximum permissible levels of pesticides in foods, which are referred to as ''tolerances'' (21 U.S.C. 346a, 348). Under the FFDCA, a tolerance is required for pesticide residues in food for consumption by humans or by food animals. Without such a tolerance or an exemption from a tolerance, a food or

feed 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. 342). Monitoring and enforcement of pesticide residues are carried out by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA).

The FFDCA governs tolerances for raw agricultural commodities (RACs) and processed foods separately. For pesticide residues in or on RACs, EPA establishes tolerances, or exemptions from tolerances when appropriate, under section 408. For processed foods, food additive regulations (FARs) setting maximum permissible levels of pesticide residues are established under section 409. Section 409 FARs are needed, however, only for certain pesticide residues in processed food. Under section 402(a)(2) of the FFDCA, no section 409 FAR is required if any pesticide residue in a processed food, when ready to eat, is equal to or below the tolerance for that pesticide in or on the RAC from which it was derived and all other conditions of section 402(a)(2) are met. 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 necessary to prevent foods from being deemed adulterated when the concentration of the pesticide residue in a processed food is greater than the tolerance prescribed for the RAC, or if the processed food itself is treated or comes in contact with a pesticide.

If a food additive regulation must be established, section 409 of the FFDCA requires that the use of the pesticide will be ''safe'' (21 U.S.C. 348(c)(3)). Section 409 also contains the Delaney clause, which specifically provides that, with little exception, ''no additive shall be deemed safe if it has been found to induce cancer when ingested by man or animal'' (21 U.S.C. 348(c)(3)).

B. Regulatory Background

1. *Les v. Reilly.* On May 25, 1989, the State of California, the Natural Resources Defense Council, Public Citizen, the AFL-CIO, and several individuals filed a petition requesting that EPA revoke several food additive regulations. The petitioners argued that these food additive regulations should be revoked because they violate the Delaney clause.

EPA responded to the petition by revoking certain food additive regulations, but retained several others on the grounds that the Delaney clause provides an exception for pesticide residues posing *de minimis* risk. EPA denied the petition for the food additive regulations determined to fall under this exception. EPA's response was challenged by the petitioners in the U.S. Court of Appeals, Ninth Circuit. On July 8, 1992, the court ruled in *Les v. Reilly,* 968 F.2d 985 (9th Cir.), cert. denied, 113 S.Ct. 1361 (1993), that the Delaney clause of section 409 barred the establishment of a food additive regulation for pesticides which ''induce cancer,'' even if the risks are considered *de minimis.* In response to the court's decision in *Les v. Reilly,* EPA has taken steps to identify and revoke all section 409 FARs for pesticides which ''induce cancer.'' In the Federal Register of March 30, 1994 (59 FR 14980), EPA issued a list of pesticide uses which were likely to be affected by the court's decision. (Note that for the purpose of this document, the list has been superseded by Appendices to the court-approved settlement in *California v. Browner,* discussed below.)

EPA first revoked certain FARs of six pesticides that were the subject of the original NRDC petition. (58 FR 37862, 58 FR 59663 and 59 FR 10993). A number of these actions have been challenged in court; some have been stayed. EPA decided to evaluate the remaining FARs potentially inconsistent with the Delaney clause in phases. The first two phases focused on processed human foods. EPA proposed the first set of revocations, including 26 FARs for seven pesticides, in the Federal Register of July 1, 1994 (59 FR 33941). A second set of proposed revocations, including six FARs for four pesticides, was published in the Federal Register of January 18, 1995 (60 FR 3607). These two proposed revocations have not yet been finalized. This document, which focuses on FARs for animal feeds, completes EPA's review of the FARs earlier identified as potentially inconsistent with the Delaney clause.

2. *California v. Browner.* In a court-approved settlement, entered on February 9, 1995, in the case of *California v. Browner,* EPA agreed to make decisions regarding pesticides that may be affected by the Delaney clause. This settlement agreement includes Appendices listing pesticides and uses upon which EPA must make decisions and a timetable for making the decisions. The settlement required EPA to rule on the NFPA petition that challenged a number of policies under which EPA administers its tolerance-setting program. This document is consistent with the timeframes in that settlement.

In the Federal Register of June 14, 1995 (60 FR 31300), EPA issued a partial response to the NFPA petition. In that document, EPA concluded that some changes were warranted to its policies concerning application of the Delaney clause. The proposals below in this document are consistent with these new policies.

III. Revised Agency Policies, Guidelines, and Legal Interpretations

A. Concentration and ''Ready to Eat'' Policies

To determine whether the use of a pesticide on a growing crop needs a section 409 FAR in addition to a section 408 tolerance, EPA looks at the likelihood that the residue levels in the processed food will exceed the section 408 tolerance level. In the past, EPA applied this policy focusing almost exclusively on the results of processing studies using treated crops. In response to the NFPA petition, EPA announced new policies on how it would determine whether a pesticide needs a section 409 FAR. EPA stated that it would consider a greater range of information in determining the likelihood of residues in processed food exceeding the section 408 tolerance. EPA also adopted a definition of ''ready to eat'' (RTE) as it applies to human food and animal feed. Whether a food is RTE or not is critical to application of the concentration policy. If a food is not RTE, EPA must consider the degree of dilution that occurs in producing a RTE food from the not-RTE food in determining the likelihood that residues in RTE food will exceed the section 408 tolerance.

Perhaps the most significant new information that EPA stated it would consider is information bearing on the average residue value from crop field trials. The data from field residue trials show that it is possible to obtain significantly different residue values from multiple field trials. EPA concluded that where a crop is mixed or blended during processing, it would be appropriate to use an average residue value rather than the highest field trial sample value in estimating the potential level of residue in processed food. As EPA noted, EPA believes that generally the most appropriate average value to use is the highest average field trial (HAFT) value. Consequently, EPA revised its procedures and is now using the HAFT as the basis for determining whether a section 409 FAR is needed.

Another outcome of the new concentration policy is that EPA has revised its policies for the use of multiple processing studies. EPA may receive several processing studies for a

crop, with each showing a different concentration factor. When different concentration factors result from multiple processing studies, EPA will now use the average concentration factor to determine concentration. EPA explained the basis for this change in its response to comments filed on the NFPA petition. In addition, EPA is examining processing studies to ensure that they reflect typical commercial practices. If a study does not include a step (e.g., washing) that is considered typical practice in processing an RAC, EPA may not include that study in the calculation of the average concentration factor.

In response to the NFPA petition, EPA stated it would interpret the phrase RTE food as meaning food ready for consumption ''as is'' without further preparation. EPA also announced that it will apply a similar approach to processing byproducts used as animal feeds. With regard to animal feed, EPA announced that if a feed item is considered unpalatable when fed ''as is'' or if for nutritional or other reasons the feed item is generally further processed or mixed, EPA will consider that feed item not RTE. EPA has applied this new interpretation on a case-by-case basis in making determinations on several of the feed items that are the subject of this document.

B. Guidelines on Significant Animal Feeds

EPA requires processing data and sets tolerances and FARs only on animal feeds that are consumed in significant amounts in the United States. Table II of the Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, provides a listing of all significant food and feed commodities, both raw and processed, for which residue data are collected and tolerances or FARs are established. On June 8, 1994, EPA revised Table II and sought comments on these revisions (59 FR 29603). In response, EPA received extensive new data and many comments concerning the amounts of raw agricultural commodities and processing byproducts that are used as animal feeds. As a result, EPA has updated Table II and modified its guidelines regarding which raw commodities and processing byproducts EPA will consider as animal feeds possibly requiring FARs.

The general cutoff point used by EPA in deciding which feed items are considered ''significant'' is whether the feed item constitutes greater than 0.04 percent, by weight, of the total feed available to livestock in the U.S. However, feed items constituting less than 0.04 percent are also considered significant if:

1. Greater than 10,000 tons are fed annually (ca. 0.0015% of total feed), and the crop is grown exclusively for use as animal feed (e.g., vetch); or

2. The feed is of particular regional concern (e.g., animal feeds likely to result in residues in regionally produced commodities such as milk and eggs) or has had historical incidence issues (e.g., pineapple process residue); or

3. The feed is included in commodities market listings and is thus traded and likely to be found in interstate commerce. Using these criteria, approximately 99.8% of feeds available to livestock in the U.S. are accounted for in the updated Table II.

Although many feed items, including processing byproducts, are no longer included in Table II as a result of the new information used to revise the table, these commodities combined represent less than 0.2 percent by weight of total livestock feeds. The percentage represented by any single feed item is negligible.

Elsewhere in this issue of the Federal Register, EPA is issuing a Notice of Availability of the revised table.

C. DES Proviso

The Delaney clause in section 409 of the FFDCA contains an exception for animal feed additives that do not harm the animal and are not found in the resulting animal food products by an analytical method approved or prescribed by FDA or EPA as applicable. In full, this exception reads:

The Delaney clause shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds:

(i) That, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended; and

(ii) That no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, * * *) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal. 21 U.S.C. 348(c)(3)(A).

This exception historically has been referred to as the ''DES proviso'' because it was enacted, in part, in response to the use of the animal drug diethylstilbestrol (DES). A similar provision is included in the Delaney clauses in the color additives and animal drug provisions of the FFDCA. See 21 U.S.C. 360b(d)(1)(I) and 379e(b)(5)(B).

FDA has a long history of rulemaking on the DES proviso. FDA's current regulations regarding the DES proviso codify what FDA has described as a ''sensitivity of method'' (SOM) approach. In brief, the SOM approach uses quantitative risk assessment to define a level of residue in the edible animal product which represents no more than a 1-in-1 million lifetime risk. This residue level is then taken to represent an insignificant risk level to the public, and FDA designates that residue level and below as ''no residue'' under the DES proviso whether or not such residues are detected by the approved method. See 21 CFR 500.84. Additionally, under the SOM approach, FDA requires sponsors of compounds to develop analytical methods which are at least sensitive enough to measure residues down to the level of residue corresponding to an insignificant risk. 21 CFR 500.88.

Although the DES proviso and the SOM approach were not part of the *Les v. Reilly* decision, EPA undertook a full review of its policies related to the Delaney clause including the SOM approach in the wake of that decision. For that reason, EPA requested comment on the SOM approach in its notice announcing receipt of the NFPA petition. 58 FR 7474 (February 5, 1993). After reviewing the comment received and after consulting with FDA and the Department of Justice, EPA has decided generally to continue to rely on the SOM approach including taking risk considerations into account in determining whether an analytical method is sufficiently sensitive to be approved. EPA, however, will not rely on one aspect of the SOM approach. EPA will not rely upon estimates of risks posed by residues to designate a ''no residue'' level, at or below which residues are presumed not to be found. Rather, EPA will determine whether residues could be found by (1) determining the level of residue expected in animal products given the conditions of use of the pesticide and the levels of residue expected in feed, and then (2) examining whether the approved method could detect such residue levels in animal products. If the method could detect the residues expected in animal products (even residues below the risk level determined under the SOM approach), then these residues would be considered to be ''found'' under the DES proviso, and the DES proviso could not be invoked as an exception to the Delaney clause.

EPA does not anticipate that this approach to determining whether

residues are ''found'' will change the substance of EPA's current practices involving method development and approval. As required by the DES proviso, however, EPA will formally approve methods by regulation when the DES proviso is invoked to support a FAR. EPA will not approve a method, and therefore not exercise the DES proviso, if the method cannot detect residues that the Agency considers to pose a risk of concern.

EPA believes that its decision to interpret the DES proviso as imposing a strict detectability standard is consistent with the plain language of the statute. The DES proviso requires that ''no residue of the additive will be found [] by methods of examination prescribed or approved by the Secretary * * * .'' The use of the term ''found'' and the express mention of analytical methods support reading the DES proviso as imposing a detectability test. This conclusion is confirmed by the legislative history which shows both that Congress understood that the DES proviso imposed a detectability standard and that Congress was opposed to the principle that any detected residue of a carcinogen could be found to be safe.

The prior justification for the taking risk into account in determining whether residues are ''found'' was that a literal approach to the term ''no residue'' would render the DES proviso meaningless because scientists could never conclude that a substance introduced into an animal left absolutely no molecules of residue in edible animal products. (52 FR 49572, December 31, 1987). To avoid construing the DES proviso so as to render it inconsequential, the concept of risk was introduced as a way of defining ''no residue.'' After further evaluation, EPA believes that reading the DES proviso as imposing a detectability standard is both consistent with the statutory language and avoids making the DES proviso a meaningless provision. EPA's experience has been that the presence of pesticide residues in animal feeds often does not lead to detectable residues in edible animal products. EPA regulations in 40 CFR 180.6 reflect that experience by explicitly directing that no tolerance for pesticide residues in animal products is required when appropriate studies show that detectable residues are not reasonably expected.

IV. Decision Framework

In analyzing whether the 36 FARs addressed in this document should be revoked, EPA has used the following decision framework. First, EPA determined whether a section 409 FAR is necessary to prevent adulteration, given the revisions to the animal feed guidelines, the concentration policy, or new data which have been submitted. If application of the revised guidelines and concentration policy shows no FAR is needed, this document proposes that the FAR be revoked on that ground. Second, if this analysis showed that a FAR is still needed, then the FAR's consistency with the Delaney clause was analyzed.

In examining whether a FAR was needed, EPA followed a stepwise process involving a series of questions. In brief, the questions are:

A. Significant Animal Feed

Is the feed for which the FAR was established a significant animal feed? EPA has updated its table of significant animal feeds. In the process, the Agency has identified a number of processed animal feed items that are not significant according to the criteria in Unit. III.B. of this preamble. If the animal feed for which the FAR was established has been dropped from the list of significant animal feeds, the FAR is not necessary.

B. Concentration Policy Including RTE

1. *Using highest average residue value from field trials (HAFT), do residues in processed food exceed the section 408 tolerance?* Use of the HAFT for feed commodities that are likely to be mixed or blended decreases the likelihood that residues in processed feed will exceed the section 408 tolerance. Typically, EPA would determine the HAFT as part of its review of field residue data for a new tolerance. For the pesticides that are the subject of this proposed rule, however, EPA did not determine the HAFT in most cases, because other factors, notably new processing studies and use of average concentration factors, were sufficient for EPA to conclude that residues would not exceed the 408 tolerance.

2. *Do processing data show that there is concentration of residues during processing?* If processing studies demonstrate that the level of residues in the processed animal feed is less than the level of residues in the precursor crop (i.e., no ''concentration in fact''), a FAR is unnecessary. For some pesticides subject to this proposed rule, EPA has received new processing studies which change its previous conclusion that concentration occurs in processing.

3. *Does use of the average concentration factor show that there is concentration of residues during processing?* Use of the average concentration factor from multiple processing studies generally decreases the likelihood that residues in the processed animal feed will exceed the section 408 tolerance.

4. *Is the dilution that occurs during preparation of RTE animal feed sufficient to reduce pesticide residues below the section 408 tolerance?* If a processed feed item is not fed to animals ''as is,'' EPA must evaluate the expected residue level in RTE animal feed containing the processed feed item. EPA has determined that many of processed feed items covered by the FARs addressed in this proposal are not RTE. Information available to EPA shows that processed feed items are rarely fed to animals singly or ''as is,'' that they are typically mixed or blended with other feed items to create a finished RTE feed. Blending of processed feed items is necessary to make them palatable or to ensure that the animal receives a nutritionally sufficient diet. For example, soybean hulls by themselves are neither palatable to animals nor an adequate nutritional source, and are therefore fed only in a feed mixture.

To determine the levels of pesticides residues in the RTE animal feed, EPA obtained information on the amount of dilution that occurs from mixing and blending feed items into finished feeds (a ''dilution factor''). Since the amount of dilution in finished animal feeds varies due to differences in animal dietary needs, EPA used the lowest dilution factor (the highest level of potential residues in finished feed) in its determinations. If the dilution of residues resulting from mixing and blending is greater than the concentration of residues resulting from processing (the dilution factor is greater than the concentration factor), it is likely that the residues in the finished RTE feed will be less than the section 408 tolerance. In this case, no FAR is necessary for the RTE animal feed.

5. *Does a combination of concentration factors show that it is unlikely that the residues in processed food will exceed the section 408 tolerance*? For some pesticides, the factors analyzed individually might indicate that residues exceed the section 408 tolerance, but when analyzed in combination they allow EPA to conclude that, in actuality, residues are not likely to exceed the section 408 tolerance. Therefore, the final step in this analysis was to look at the above factors in combination to determine if a FAR is needed.

If, after consideration of the above factors, a FAR is determined to be necessary, EPA then examined whether

a FAR for the pesticide chemical is consistent with the Delaney clause. That examination focused on whether the pesticide induces cancer within the meaning of the Delaney clause. If EPA concluded that the pesticide induces cancer, then EPA determined whether the FAR is nonetheless excepted from the Delaney clause prohibition by the DES proviso.

V. EPA's Decisions

Based on the above analyses, EPA proposes to revoke 34 FARs on the basis that they are not needed to prevent adulterated food and two FARs because they violate the Delaney clause.

A. Food Additive Regulation Is Not Needed

1. *Not considered significant feed item*. As a result of the updating of the guideline on significant animal feeds, 16 of the 36 FARs are no longer considered necessary. EPA proposes to revoke on this ground the following FARs: (1) benomyl on dried apple pomace, dried grape pomace and raisin waste; (2) diflubenzuron on soybean soapstock; (3) iprodione on dried grape pomace, raisin waste, and peanut soapstock; (4) mancozeb on milled fractions of barley, oats, and rye; (5) norflurazon on citrus molasses; (6) propargite on dried apple pomace and dried grape pomace; (7) thiophanate-methyl on dried apple pomace; and (8) triadimefon on wet/dry grape pomace and raisin waste. Documentation explaining EPA's conclusions on what animal feeds are significant is included in the docket.

After this reassessment, only 20 of the original 36 FARs require further consideration.

2. *Revised concentration policy including RTE—i. Highest average field trial value.* Consideration of HAFT values from crop field trials did not alone affect whether any FARs were needed. (The HAFT was considered in combination with other factors in determining that a tolerance for diflubenzuron on soybean hulls was not necessary.)

ii. *New processing study*. EPA has received new processing studies that show that 4 of the remaining FARs are unnecessary because processing results in no concentration in fact of residues. EPA proposes to revoke on this ground the following FARs: (1) dimethipin on cottonseed hulls; (2) norflurazon on dried citrus pulp; (3) propargite on dried citrus pulp; and (4) thiodicarb on cottonseed hulls. Documentation on these new processing studies is included in the docket.

After this reassessment, only 16 of the original 36 FARs require further consideration.

iii. *Average concentration factor shows no concentration in fact.* Calculation of the average concentration factor from more than one processing study shows that 4 of the remaining FARs are unnecessary because processing results in no concentration in fact of residues. EPA proposes to revoke on this ground the following FARs: (1) acephate on cottonseed meal and soybean meal; (2) carbaryl on pineapple bran; and (3) dimethoate on dried citrus pulp. Documentation on the calculation of the average concentration factors is included in the docket.

After this reassessment, only 12 of the original 36 FARs require further consideration.

iv. *Dilution factor is greater than concentration factor during processing* For the remaining FARs, EPA concluded that the following processed feed items are not RTE: Cottonseed hulls, dried citrus pulp, rice bran and hulls, milled fractions of wheat, and soybean hulls.

EPA concluded that the following processed feed item is RTE: Sugarcane molasses.

Evaluation of the degree of dilution involved in the preparation of RTE animal feeds from not-RTE processed feed items showed that 8 of the remaining FARs are unnecessary because residues are unlikely to exceed the section 408 tolerance in the RTE animal feeds. EPA proposes to revoke on this ground the following FARs: (1) acephate on cottonseed hulls; (2) benomyl on dried citrus pulp and rice hulls; (3) imazalil on dried citrus pulp; (4) iprodione on rice bran and rice hulls; (5) mancozeb on milled fractions of wheat; and (6) thiodicarb on soybean hulls.

For these pesticide/processed feed item combinations, EPA plans to use its general rulemaking authority under FFDCA sec. 701, to establish maximum residue levels. Documentation of EPA's conclusions regarding concentration factors, RTE status, and dilution factors for these processed feed items is provided in the docket.

After this reassessment, only 4 of the original 36 FARs require further consideration.

v. *Combination of factors.* Analysis of the combined effect of the use of the above factors for RTE feeds showed that two of the remaining FARs are unnecessary. EPA is proposing to revoke on this ground the FARs for diflubenzuron on soybean hulls and triadimefon on wet apple pomace.

The tolerance for diflubenzuron in soybeans is at the limit of quantification (LOQ) of the analytical method (0.05 ppm). A single processing study shows residues of diflubenzuron in soybean hulls concentrate to eight times the soybean level. Using the HAFT of 0.03 ppm obtained using a more sensitive analytical method, a concentration factor of 8 and a dilution factor of 4 for soybean hulls, residues in finished RTE feed are calculated to be 0.06 ppm (0.03 X 8 divided by 4). This is within the limit of analytical variability of the LOQ tolerance of 0.05 ppm. Documentation on consideration of these factors for this FAR is provided in the docket.

Several factors were considered in the determination as to whether the feed additive tolerance for triadimefon on wet apple pomace is still necessary. (The existing feed additive tolerance covers both wet and dry apple pomace; however, dry apple pomace is no longer considered a significant feed item.) All registered uses of triadimefon on apples have been amended to extend the preharvest interval (PHI) from 0 days to 45 days. Available residue data reflecting a 45-day PHI support a tolerance of 0.2 ppm on raw apples. The HAFT from these studies is 0.09 ppm, and a new processing study indicates a concentration factor of 1.6X for residues in wet apple pomace. Residues in wet apple pomace can thus be calculated as 0.09 ppm X 1.6 = 0.14 ppm, which is below the 0.2-ppm tolerance needed for apples. Therefore, a section 409 tolerance for wet apple pomace is not required.

After this reassessment, only 2 of the original 36 FARs require further consideration.

B. Food Additive Regulation is Needed

EPA has determined that one of the remaining FARs is necessary because the application of the pesticide to the RAC could lead to residues in RTE processed feed that exceed the applicable section 408 tolerance. This is simazine on sugarcane molasses. Documentation as to why this FAR is needed under the revised concentration policy is included in the docket.

The last FAR, tetrachlorvinphos in processed feed items, is needed because it is a direct additive to processed animal feed. None of the above factors is relevant to a direct additive to processed animal feeds.

C. Induce Cancer Call for Pesticides that Need 409s

If a FAR is necessary to prevent adulterated food, as in the case of the two pesticides named in Unit V.B. above, EPA next determined whether the pesticide induces cancer within the meaning of the Delaney clause.

In construing the ''induce cancer'' standard as to animals, EPA follows a weight-of-the-evidence approach. In regard to animal carcinogenicity, EPA, in general, interprets ''induces cancer'' to mean:

The carcinogenicity of a substance in animals is established when administration in an adequately designed and conducted study or studies results in an increase in the incidence of one or more types of malignant (or, where appropriate, benign or a combination of benign and malignant) neoplasms in treated animals compared to untreated animals maintained under identical conditions except for exposure to the test compound. Determination that the incidence of neoplasms increases as the result of exposure to the test compound requires a full biological, pathological, and statistical evaluation. Statistics assist in evaluating the biological significance of the observed responses, but a conclusion on carcinogenicity is not determined on the basis of statistics alone. Under this approach, a substance may be found to ''induce cancer'' in animals despite the fact that increased tumor incidence occurs only at high doses, or that only benign tumors occur, and despite negative results in other animal feeding studies. (See 58 FR 37863, July 14, 1993; 53 FR 41108, October 19, 1988; and 52 FR 49577, December 31, 1987).

In a proposed revocation issued in 1994, EPA concluded that simazine meets this standard. EPA is currently considering comments on this proposal. EPA believes that tetrachlorvinphos also qualifies as an animal carcinogen under this test.

Summarized below is the information supporting EPA's determination that tetrachlorvinphos induces cancer. Full copies of each of these reviews and other references in this document are available in the OPP Docket, the location of which is given under ''ADDRESSES'' above. Information on simazine is contained in OPP Docket OPP-300335.

Tetrachlorvinphos

After a full evaluation of the data and supporting information regarding animal carcinogenicity, EPA concludes that exposure to tetrachlorvinphos results in an increased incidence of hepatocellular carcinomas and combined adenomas/carcinomas (predominantly malignant carcinomas) in female B6C3Fl mice.

In male mice there are also increases in hepatocellular combined adenomas/carcinomas and tumors of the kidney (carcinomas, adenomas and combined adenomas/carcinomas with a large contribution from malignant carcinoma). In the male Sprague-Dawley rat there are nonsignificant increases in adrenal benign pheochromocytomas (significant positive trend) and thyroid C-cell adenomas. These latter two tumor types are consistent with the same tumor types observed in another earlier study in Osborne-Mendel rats.

The mutagenicity data for tetrachlorvinphos demonstrate clastogenic activity, which supports a carcinogenicity concern. Analogs structurally similar to tetrachlorvinphos (DDVP and phosphamidon) are also carcinogenic. Tetrachlorvinphos can undergo hydrolysis and then tautomerize to generate a potentially carcinogenic reactive ketone intermediate.

Discussions of the various studies on the carcinogenicity of tetrachlorvinphos can be found in the Peer Review of tetrachlorvinphos (Dec. 12, 1994) in the docket.

D. DES Proviso

EPA may establish or maintain a section 409 FAR for a pesticide that induces cancer only if the DES proviso excludes it from the Delaney clause (see Unit III.C. of this preamble). When a pesticide needing a FAR is found to induce cancer, the final step in the analysis is to determine if the FAR is nonetheless excepted from the Delaney clause prohibition by the DES proviso.

The DES proviso applies when no detectable residues are expected in the animal commodities (meat, milk, poultry, eggs) as a result of animal consumption of feeds containing tolerance level residues. If no detectable residues of the chemical can be found in the animal commodities, the FAR can be maintained or established.

1. *Tetrachlorvinphos*. EPA concludes that the DES proviso does not except the tetrachlorvinphos FAR from the Delaney clause. The tetrachlorvinphos FAR does not qualify because the existing enforcement method has not been approved under the DES proviso and EPA does not believe it would be appropriate to approve that method because it determines residues of parent only and not several metabolites of carcinogenic concern. Moreover, EPA has estimated, if a method covering these metabolites were developed, the method would be expected to be able to detect residues of tetrachlorvinphos in animal products, assuming the method is of comparable sensitivity to the existing method.

2. *Simazine*. EPA has concluded that the DES proviso does not except the simazine FAR from the Delaney clause. Using the existing enforcement method for simazine, EPA has estimated, residues of simazine will not be found in edible products of animals. However this enforcement method has not been approved by regulation for use by applying the DES proviso and EPA does not believe the method is sufficiently sensitive that it should be approved. As FDA's regulations concerning the DES proviso make clear, methods used in applying the DES proviso must be capable of detecting residues at a level representing a maximum lifetime cancer risk of 1-in-1 million. 21 CFR 500.88(b). The current enforcement method for simazine detects residues in edible animal products only down to a level representing a lifetime cancer risk from simazine in such products of approximately 1 in 100,000. Because this method is not sufficiently sensitive, EPA is not proposing it for approval, and therefore EPA cannot conclude that the DES proviso is available to exempt the simazine FAR from the Delaney clause. If a method for simazine is available that has greater sensitivity, EPA will reexamine the question of whether the DES proviso does apply.

VI. Proposed Rules

A. Proposed Revocations: Section 409 FAR Is Not Needed.

EPA is proposing to revoke the following 34 of the original 36 FARs because the Agency has determined they are not needed:

Name of pesticide	40 CFR cite	Processed feed item
Acephate	186.100	Cottonseed meal, cottonseed hulls, soybean meal
Benomyl	186.350	Dried apple pomace, dried citrus pulp, dried grape pomace, raisin waste, rice hulls
Carbaryl	186.550	Pineapple bran (wet and dry)
Diflubenzuron	186.2000	Soybean hulls, soybean soapstock
Dimethipin	186.2050	Cottonseed hulls

Name of pesticide	40 CFR cite	Processed feed item
Dimethoate	186.2100	Dried citrus pulp
Imazalil	186.3650	Dried citrus pulp
Iprodione	186.3750	Dried grape pomace, raisin waste, peanut soapstock, rice bran, rice hulls
Mancozeb	186.6300	Milled barley fractions, milled oat fractions, milled rye fractions, milled wheat fractions
Norflurazon	186.4450	Dried citrus pulp, citrus molasses
Propargite	186.5000	Dried apple pomace, dried citrus pulp, dried grape pomace
Thiodicarb	186.5650	Cottonseed hulls, soybean hulls
Thiophanate-methyl	186.5700	Dried apple pomace
Triadimefon	186.800	Grape pomace (wet and dry), raisin waste, apple pomace (wet/dry)

B. Proposed Revocations: Violates Delaney Clause

1. *Tetrachlorvinphos*. EPA is proposing to revoke the FAR for tetrachlorvinphos (2-chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate) when used as a direct feed additive. This FAR is codified at 40 CFR 186.950. EPA is proposing to revoke this FAR because EPA has determined that tetrachlorvinphos induces cancer in animals. Because a section 409 FAR is required and the DES proviso does not apply, the regulation violates the Delaney clause in section 409 of the FFDCA.

2. *Simazine*. EPA is proposing to revoke the FAR for simazine residues on sugarcane molasses. This FAR is codified at 40 CFR 186.5350. EPA is proposing to revoke this FAR because EPA has determined that simazine induces cancer in animals. Because a section 409 FAR is required and the DES proviso does not apply, the regulation violates the Delaney clause in section 409 of the FFDCA.

VII. Consideration of Comments

Any interested person may submit comments on this proposed action to the address given in the ''ADDRESSES'' section (see above). Before issuing a final rule based on this proposal, EPA will consider all relevant comments. EPA also welcomes comment on whether its proposed revocations issued on July 1, 1994 (59 FR 33941; OPP Docket 300335) and January 18, 1995 (60 FR 3607; OPP Docket 300360) should be revised based on the changed policies and guidelines discussed in this proposed rule. Any comment on these prior proposals should bear their appropriate OPP docket control numbers. After consideration of comments, EPA will issue a final order determining whether revocation of the regulations is appropriate. Such order will be subject to objections pursuant to section 409(f) (21 U.S.C. 348(f)). Failure to file an objection within the appointed period will constitute waiver of the right to raise issues resolved in the order in future proceedings.

A record has been established for this rulemaking under docket number [OPP-300397] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-Docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

VIII. Executive Order 12866

EPA believes that there will be no significant economic impacts from this action. Revocation of 34 unnecessary tolerances does not affect the availability of the pesticides for use on the crops involved. EPA has not completed an evaluation of the economic impacts of this particular action for the two proposed revocations under the Delaney clause, since the Delaney clause requires EPA to act without considering the costs or benefits of the action. Nevertheless, EPA believes that the revocation of simazine on sugarcane molasses and tetrachlorvinphos on processed animal feed will have little economic impact.

Simazine residues on domestically produced molasses are assumed to be zero since simazine is no longer registered for use on sugarcane domestically. No impacts are expected to U.S. sugarcane growers from this proposed revocation. However, there could be short-term impacts to the domestic market due to decreased supply or increased price for imported molasses for animal feed. EPA cannot accurately estimate the amount of molasses from sugarcane that is imported to the U.S. Data on sugarcane molasses are generally aggregated with other molasses imports. Moreover, EPA lacks information on pesticide usage from some countries with significant molasses exportation. However, based on available information from countries for which EPA has data and alternative sources of molasses, EPA believes impacts upon domestic users of molasses will be minor and temporary.

Tetrachlorvinphos is used as a feed-through insecticide for control of flies on cattle, hogs, and horses. The bulk is used as a cattle feed-through; little is used for hogs or horses. Both diflubenzuron and methoprene are registered alternatives for cattle. For hogs and horses, although there are no feed-through alternatives available, dimethoate, cyromazine, and dichlorvos are available as nonfeed-through alternatives, and tetrachlorvinphos remains available for direct application to animals. Given that the costs of some of the alternatives are less than tetrachlorvinphos, alternatives exist, and dermal applications are permitted, EPA believes that there will be no significant adverse economic effects

from revocation of the animal feed tolerance for tetrachlorvinphos.

IX. Regulatory Flexibility Act

As explained above, the Agency is compelled to take this action without regard to the economic impacts, including impacts on small businesses. Therefore, this rule has not been reviewed under the provisions of sec. 3(a) of the Regulatory Flexibility Act.

X. Paperwork Reduction Act

There are no information collection requirements in this proposed order.

List of Subjects in 40 CFR Part 186

Environmental protection, Agricultural commodities, Pesticides and pests, Feed additives, Reporting and recordkeeping requirements.

Dated: September 15, 1995.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR part 186 be amended as follows:

PART 186—[AMENDED]

1. The authority citation for part 186 continues to read as follows:

Authority: 2l U.S.C. 348.

§ 186.100 [Removed]

2. By removing § 186.100 *Acephate.*

§ 186.350 [Removed]

3. By removing § 186.350 *Benomyl.*

§ 186.550 [Removed]

4. By removing § 186.550 *Carbaryl.*

§ 186.800 [Removed]

5. By removing § 186.800 *1-(4-chlorophenoxy)-3,3-dimethyl -1-(1H-1,2,4-triazol-1-yl)-2-butanone.*

§ 186.950 [Removed]

6. By removing § 186.950 *2-Chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate.*

§ 186.2000 [Removed]

7. By removing § 186.2000 *Diflubenzuron.*

§ 186.2050 [Removed]

8. By removing § 186.2050 *Dimethipin.*

§ 186.2100 [Removed]

9. By removing § 186.2100 *Dimethoate including its oxygen analog.*

§ 186.3650 [Removed]

10. By removing § 186.3650 *Imazalil.*

§ 186.3750 [Removed]

11. By removing § 186.3750 *Iprodione.*

§ 186.4450 [Removed]

12. By removing § 186.4450 *Norflurazon.*

§ 186.5000 [Removed]

13. By removing § 186.5000 *Propargite.*

§ 186.5350 [Removed]

14. By removing § 186.5350 *Simazine.*

§ 186.5650 [Removed]

15. By removing § 186.5650 *Thiodicarb.*

§ 186.5700 [Removed]

16. By removing § 186.5700 *Thiophanate-methyl.*

§ 186.6300 [Removed]

17. By removing § 186.6300 *Zinc ion and maneb coordination product.*

[FR Doc. 95–23443 Filed 9–18–95; 1:26 pm]

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