

**COMMENTS OF
THE IMPLEMENTATION WORKING GROUP
ON
THE FOOD AND DRUG ADMINISTRATION'S
“ CHANNELS OF TRADE POLICY FOR COMMODITIES
WITH RESIDUES OF PESTICIDE CHEMICALS FOR WHICH
TOLERANCES HAVE BEEN REVOKED, SUSPENDED, OR MODIFIED
BY THE ENVIRONMENTAL PROTECTION AGENCY–
DRAFT GUIDANCE,”
68 FR 43535, JULY 23, 2003**

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The Implementation Working Group (IWG) is pleased to present comments on the Draft Guidance on the policy that the Food and Drug Administration (FDA) should use to implement § 408(l)(5) of the Federal Food, Drug and Cosmetic Act (FFDCA), the so-called “channels of trade” provision that allows persons who are responsible for food found to contain residues of pesticide chemicals the tolerances for which have recently been revoked by the U.S. Environmental Protection Agency (EPA) to show FDA that the residues resulted from lawful use of the pesticide and thus are themselves lawful. Public comment on the Draft Guidance was requested by FDA in the *Federal Register* notice cited above.

The IWG is a coalition of farm, food, pest management, and pesticide manufacturing organizations that have joined together to address and respond to the requirements of the Food Quality Protection Act (FQPA) and to support sound and appropriate regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the FFDCA.

The IWG believes that it is a good idea for FDA to consider and adopt a policy to guide its staff and outside stakeholders in this area. However, we think there are several areas where the Draft Guidance needs basic reworking.

BACKGROUND

A residue of a pesticide on any food ordinarily is deemed unlawful and renders the food adulterated and subject to seizure unless the pesticide residue is present at a level allowed by a tolerance established by regulation under FFDCA § 408. Prior to the passage of the FQPA in 1996, when a pesticide’s use on a particular crop was cancelled by EPA under FIFRA the corresponding tolerances for the raw agricultural commodity

(RAC) and any processed foods made from it typically were left in place for a period that EPA judged would be sufficient to allow legally treated crops and processed foods made from them to clear the channels of trade. This approach was part of EPA's "coordination policy," the goal of which was to avoid putting food producers and processors in situations where pesticide residues on food might be regarded as unlawful because a tolerance is no longer in effect, even though the residues resulted from a lawful application of the pesticide. FFDCA § 408(1)(5), added to the law by the FQPA in 1996, was an attempt to codify this practice and to not only authorize, but to require FDA¹ to conclude that food from legally treated crops was not to be deemed adulterated despite the revoked tolerance. Section 408(1)(5) states:

(5) Pesticide residues resulting from lawful application of pesticide

Notwithstanding any other provision of this chapter, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary that—

(A) the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under the Federal Insecticide, Fungicide, and Rodenticide Act; and

(B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this chapter;

unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e) of this section, the Administrator has issued a determination that consumption of the legally treated food

¹ As the Draft Guidance notes, FDA's enforcement authority under the FFDCA does not extend to meat, milk, and certain egg products, which come under the authority of the U.S. Department of Agriculture. Accordingly, the FDA Guidance would not govern enforcement with regard to those food categories. It will be very difficult to do calculations under § 408(1)(5) with regard to secondary residues in meat, milk, or eggs from livestock or poultry that have consumed feed with residues that formerly had tolerances. FDA does have authority over animal feeds; FDA should also state whether its Guidance extends to animal feed items, and if so, what aspects of its approach to animal feed, if any, will differ from its approach to human food items.

during the period of its likely availability in commerce will pose an unreasonable dietary risk.

The House Commerce Committee's report on the portion of its bill that became § 408(1)(5) says:

This provision allows continued use of existing food stocks that were treated with a lawful pesticide, thus *protecting against unnecessary destruction of legally treated food, disruption in the marketplace, and economic loss*. It also *ensures that food producers are not unfairly penalized* for legal use of pesticides that were subject to regulatory action at a subsequent date.

H.R. Rep. 104-669, Part 2, July 23, 1996, at 52-53. This is the only pertinent legislative history. We believe that the next version of the Guidance should make clear the Congressional purpose that underlies § 408(1)(5). Section 408(1)(5) clearly governs *all* situations in which a tolerance has been revoked (or otherwise modified to allow a lower residue level than formerly was allowed), whether the revocation or modification was based on dietary risk or not.

Separately, and for different reasons entirely, the FQPA also added to the FFDCa a § 408(1)(2), saying that if EPA cancels the registrations of all products for use on a particular crop for reasons that include dietary risk, the associated tolerances must be revoked within 6 months after the date the products may no longer be used on the crop.

Most tolerance revocations occur not because EPA has cancelled registrations in order to mitigate unacceptable dietary risks, but rather for a variety of other reasons. For instance, registrants from time to time decide, for economic reasons, not to maintain certain registered uses, and EPA may revoke the tolerances thereafter because they are unneeded. To give another example, very recently EPA proposed to revoke all the meat, milk, and egg RAC tolerances for a number of pesticides because it concluded there is essentially no likelihood that their use on crops will result in residues on meat, milk, or eggs and thus no need for the tolerances in question. Likewise, EPA has determined that it no longer will regard certain feed items as significant sources of nutrition for livestock, and has revoked all tolerances for such feed items.

OVERVIEW OF THE DRAFT GUIDANCE

The Draft Guidance, as presently constructed, would establish a single approach to deal with all pesticide tolerance revocation situations as regards the food categories over which FDA exercises enforcement authority under the FFDCa. Under this approach, the FDA would ascertain the last date on which the crop in question could be treated with the

pesticide in question under the cancellation order issued by EPA under FIFRA. It would then use information on how the crop is marketed to determine the last date in which any quantities of the raw/fresh crop treated with the pesticide chemical would be expected to still be found in interstate commerce. If it could do so with available information, it also would determine the date by which any lawfully applied residues would decline to unquantifiably low levels. The earlier of those two dates would be the date after which residues of the pesticide on any quantities of the raw/fresh crop no longer would be regarded as covered by the channels of trade provision. FDA would determine this date and announce it (by use of its Internet site) at or before the time that EPA revoked the tolerance. Residues found on foods before that date generally would be treated as lawful without the need for a specific showing about when the crop actually was treated with the pesticide or when the product moved in commerce. Residues found on raw/fresh foods after that date would be regarded as unlawful. FDA says it does not expect a showing could be made that such residues are lawful. Thus, for raw foods, FDA contemplates making a single decision governing the entire crop/pesticide, and does not contemplate that a “showing” regarding individual circumstances ever would be relevant.

The Draft Guidance does contemplate that the status of processed foods bearing residues of revoked tolerances would depend on the “showing” made by the party responsible for the particular quantity of the processed food. In essence, the holder of a processed food would have to show that the residues in question came as the result of the processor’s use of raw food with residues that were lawful under the approach FDA sets forth for raw foods, as discussed in the previous paragraph.

PROBLEMS WITH THE DRAFT GUIDANCE

There are several problems with the proposed FDA policy, associated primarily with the approach to fresh/raw foods. Once those problems are remedied, the approach proposed by FDA should work quite well for processed foods.

Different Provisions Are Warranted for Routine Tolerance Revocation Actions than for Those Based on Dietary-Risk Concerns

FFDCA § 408(1)(5) on its face clearly applies to all tolerance revocations, not just to those to which § 408(1)(2) applies. However, the Draft Guidance purports to establish a single approach for all situations, and it appears that FDA had in mind only the uncommon kind of revocations referred to in 408(1)(2). This can be inferred from the dates used in the examples given in the discussion on setting the “showing dates,” and also from the paperwork burden analysis that indicates only two revocations per year would occur.

According to the Draft Guidance, whenever a tolerance is to be revoked, FDA will obtain information on the last lawful use date, on residue decline time, and on marketing

practices, and will calculate and announce publicly the dates it will use to determine whether detected residues on particular lots of fresh/raw food in commerce on a particular date will be presumed lawful. Moreover, FDA says it will do this in advance of each tolerance revocation, in connection with the EPA proposal to revoke.

However, in the typical tolerance revocation situation, there is no particular concern about health risk, the tolerance revocation usually occurs several years after the corresponding registrations are cancelled, and there is no fixed date after which use of the pesticide is unlawful. Under such circumstances, the approach FDA described to determine a single cutoff date for the lawfulness of residues would be unworkable. Moreover, there would be no particular reason to expect residues, and no particular need for the investment of time and resources by FDA that is outlined in the Draft Guidance. We hope and expect that EPA will continue to allow a reasonable time to pass before revoking tolerances in connection with most cancellations, to allow sale and then use of existing stocks. We expect there also may be more revocations of tolerances on some food forms (such as the animal feed tolerances discussed earlier) while the registration of the product for use on the crop in question continues in effect. In revising the Guidance FDA should acknowledge this and explain how the agency will respond in various additional scenarios involving tolerance revocations.

FDA should state that the approach laid out in the Draft Guidance—involving advance announcement of calculated “showing dates” and a strong if not conclusive presumption against the lawfulness of raw foods found thereafter to have residues—will be used only with regard to revocations under § 408(1)(2), not to routine tolerance revocations.

Where a tolerance has been revoked by EPA because a food form is deemed an insignificant component of the diet or because residues on the food form are considered to be highly unlikely, while the registration of the product continues to allow use on the parent crop, FDA should announce that should residues of the pesticide occasionally be found on the food form, FDA ordinarily will use its prosecutorial discretion to allow distribution and sale of the food despite the presence of a residue.

Residue Decline Information Should Not Be Used to Set Dates Under § 408(1)(5)

FDA says it will always consider information on marketing practices (specifically, how long the crop would be expected to be held after harvest and before processing or sale as unprocessed food at retail) in setting a cutoff date for raw/fresh food under § 408(1)(5).

However, FDA also says that it will, when possible, use information on residue decline rate to establish a § 408(1)(5) date, if that would result in an earlier date than would result from use of the marketing practices information. Residue decline

information would have to be both crop-specific and pesticide-specific, and thus its use would be innately more complicated than use of information on marketing practices alone.

FDA will seldom if ever possess information on residue decline that is sufficient to determine how long it takes for residues of a legally applied pesticide to decline to undetectable levels. EPA's Residue Chemistry Test Guidelines, OPPTS 860.1500: Crop Field Trials, issued in August 1996, provide the following information on when residue decline data will be required (emphasis added in italics):

[OPPTS 860.1500(e)(1)(iv), at page 5]

(iv) . . . Residue decline data will be required for uses where:

(A) The pesticide is applied when the edible portion of the crop has formed.

(B) It is clear that residues may occur on the food or feed commodities at, or close to, the earliest harvest time.

The *number of decline studies* needed is *one* for crops requiring 5 to 12 total trials and *two* for crops requiring 16 to 20 total trials. These studies are included in the 5 to 12 or 16 to 20 total trials (i.e. not in addition to these numbers of trials). For a given pesticide additional decline studies will not be required crop by crop if studies on representative crops (tree fruit, root crop, leafy vegetable, grain, and fruiting vegetable) indicate residues do not increase with longer PHIs.

[OPPTS 860.1500(e)(2)(vi), at page 16:]

(vi) **Residue decline studies.** (A) . . . The *primary purpose* of these studies is to determine if residues are higher at longer PHIs than requested and the *approximate half-life of the residues*. In addition, such studies are frequently of great value for determining an appropriate tolerance when a use pattern is changed. The number of decline studies needed is one for crops requiring 5 to 12 total trials and two for crops requiring 16 to 20 total trials. These studies are included in the 5 to 12 or 16 to 20 trials (i.e. not in addition to these numbers of trials). *Decline studies will not be required for crops needing three or fewer total trials.*

(B) The design of the decline studies should include 3 to 5 sampling times in addition to the requested PHI. The *sampling times should all fall within the crop stage when harvesting could reasonably be expected to occur*. The time points should be approximately equally spaced and, where possible, represent both shorter and longer PHIs than that requested. Of course, shorter PHIs cannot be examined in the case of a use with a zero day PHI. In addition, for an at-plant/pre-plant use, the PHI is usually predetermined by the length of the growing season of the crop. Therefore, for such uses that result in quantifiable residues, petitioners should attempt to stretch the harvest period by sampling immature fruit, tubers, etc. if necessary.

(C) Only one composite sample will be required for each time point in a decline study. However, petitioners are advised to take two or more samples to prevent method and sampling variability from masking or appearing to create residue changes with time.

(D) It is anticipated that *for most pesticides residue decline studies will not be necessary for all crops*. For a given pesticide additional decline studies will not be required if studies on representative crops indicate residues do not increase with longer PHIs. This will provide *some assurance that the tolerances represent the maximum residues that will occur from proposed or registered uses of a pesticide*. The representative crop approach to be used is similar to that described in OPPTS 860.1380. *If a pesticide is to be applied to all types of crops, it is recommended that decline data be obtained on the following five representative commodities: A tree fruit, a root crop, a leafy vegetable, a grain, and a fruiting vegetable*. Some flexibility in the choice of crops will be permitted. For example, a legume vegetable could be substituted for the fruiting vegetable.

Clearly, for most pesticides, this testing regimen will not produce any decline information that is specific to each crop. Tests on five crops are said to be sufficient to represent all crops grown in this country. Moreover, tests are required of only one or two samples per crop, so that differences in decline rates on the same crop because of differences in climate or other environmental variables in different growing areas or in different years are not regarded as important. Moreover, the decline rate studies are

performed in the field prior to harvest, and may not be at all representative of decline rates on food in storage indoors.

The residue decline data requirement is designed to help EPA determine whether the proposed tolerance is sufficiently high to cover the **maximum** likely residues from the use expected to result at harvest time. The Guideline also talks about using the data to establish the “approximate” half life of the residue on the crop tested at the place and time tested. In this context, “approximate” means “plus or minus some period of time,” and there would be no way of knowing **how much** time plus or minus. This set of information is all that is likely to be available on residue decline on the crops tested, and clearly will be insufficient to serve as the basis for FDA to establish an irrebuttable presumption of illegal application and to treat samples of that crop as adulterated. Such residue decline information is not likely to be useful in most cases even to support a **rebuttable** presumption. It is unreasonable to consider that the “approximate” pre-harvest half life of a pesticide residue measured on sample in one state in one year is representative even of the “approximate” post-harvest half life of residues of the pesticide on a different variety of the **same** crop grown in a different part of the country in a different year in different climactic conditions, in the absence of data demonstrating this. The half life information for residues in one crop certainly could not be extended to other crops in an enforcement context.

In view of the facts that residue decline data will not be available for most crops, and will not be representative even when some data are available, it would make much more sense for FDA to drop the proposed approach of attempting to use residue decline data and focus instead entirely on details of the crop marketing information approach.

Problems with Framing the Presumptions as Irrebuttable

If a residue is found on a raw food in commerce (e.g., fresh carrots) later than the showing date that was established on the basis of residue decline data, the Draft Guidance says that

While a party responsible for the carrots would have the right under the law to make a showing that the residue is present as a result of a lawful application or use of the pesticide chemical, *FDA does not expect that the responsible party would be able to make such a showing* because no residues of lawfully applied pesticide chemical . . . would be expected to be detectable after [the showing date], based upon the degradation rate of the pesticide chemical..

[At page 6, emphasis added.]

The Draft Guidance goes on to say that if a residue is found on a raw food in commerce after a showing date that was established on the basis of the “last expected date of sale” of legally treated crops

the party responsible for the carrots would have the right under the law to make a showing that the residue is present as a result of a lawful application or use of the pesticide chemical, [but] *FDA does not expect that the responsible party would be able to make such a showing* because no residues of [the] lawfully applied pesticide chemical . . . would be expected to be found after [the showing date].

[At page 6, emphasis added.]

FDA is saying that if a fresh or raw food is found bearing residues in commerce after the announced date, it will use what amounts to an irrebuttable presumption that the residues did not result from legal use of the pesticide. This presumption would be based either on “known” residue decline data or last “expected” date of sale. If this language remains unchanged, it can be expected that FDA staff will read it as allowing no room for a responsible party to make the very kind of showing that the statute clearly provides for.

We have already discussed the problems with the available data on residue decline and it does not appear conceivable that such data could form the basis even for a rebuttable presumption in the overwhelming majority of situations. As for data based on marketing information, if FDA really is going to use as a criterion anything like the “last expected date of sale” of legally treated crops, it seems self-evident that if § 408(1)(5) affords responsible parties the right to show that what **actually** happened was different than what FDA determined in advance was “**expected**” to happen. The language of the Draft Guidance should be changed to make it clear that FDA is creating a **rebuttable** presumption, because FDA will not have the kind of information it would need to create an irrebuttable presumption.

For some kinds of foods it may be difficult to justify even a rebuttable presumption based on expected market clearance of the raw food. Commodities such as grains and dried beans can be stored for very long times without degradation. The commodity examples used in the Draft Guidance—strawberries, apples, and carrots—all are perishable commodities. In its final Guidance, FDA should include an example or two of how it would establish expected market clearance dates for nonperishable foods.

Problems with Applying FFDCA § 408(1)(5) to Imported Foods

FIFRA does not apply to the sale or use of pesticides in countries other than the United States, or to food imported from such countries into the United States. This

introduces a difficulty in determining how to apply FFDCA § 408(1)(5) to imported foods that bear residues of pesticides for which tolerances have been revoked recently. The section states that the channels-of-trade-exception applies only if “the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under” FIFRA. But FIFRA neither condones nor forbids use of a pesticide in another country. The section thus could be read as meaning that it only applies to domestically grown food and provides no protection to imported food (because pesticide use in other countries is not made lawful by FIFRA). Or it could be read as meaning that as long as the pesticide was used in another country before the tolerance was revoked, the resulting imported food is entitled to the protection of the section (because pesticide use in other countries is not made unlawful by FIFRA) even if the pesticide was applied after that would have been unlawful under FIFRA in this country.

Compounding the difficulty flowing from the language of the statute are four additional factors. First, growers in other countries might be perceived as having an unfair advantage over domestic growers if § 408(1)(5) was applied differently depending on a food’s country of origin (although any advantage foreign growers would receive because of this would only persist for a few months, assuming that the Policy would only be used with regard to § 408(1)(2) revocations, as we have urged is appropriate). Second, the growing season for a crop may be different in other countries than in the United States (particularly those in the southern hemisphere). Thus, if EPA sets a “stop-use” date that is well after the end of a growing season here, that date may be in the middle of a growing season in some other countries. Third, there may be no suitable notice mechanisms to inform growers in other countries about actions under FIFRA. Fourth, a tolerance for a pesticide on a commodity might be revoked even if the commodity is not grown in this country or if the pesticide is hardly ever used here to produce the commodity, and thus little reason to be concerned about strict uniformity of treatment.

The Draft Guidance does not discuss these issues at all. It simply says, in effect, that imported food will be treated as if it were grown in this country, and the dates and timelines, beginning with the last date under which use here is lawful under FIFRA, would be applied without change to imported foods. We are concerned that applying the Guidance in the manner FDA has proposed may cause disruptions, international disputes, or retaliatory moves. FDA should either modify its stance to allow imports as long as it appears the pesticide residue resulted from application before the date of tolerance revocation, or work with EPA and exporting countries to reach agreements about notification and phase-out procedures so that foreign growers and domestic importers are not placed at unnecessary disadvantage.