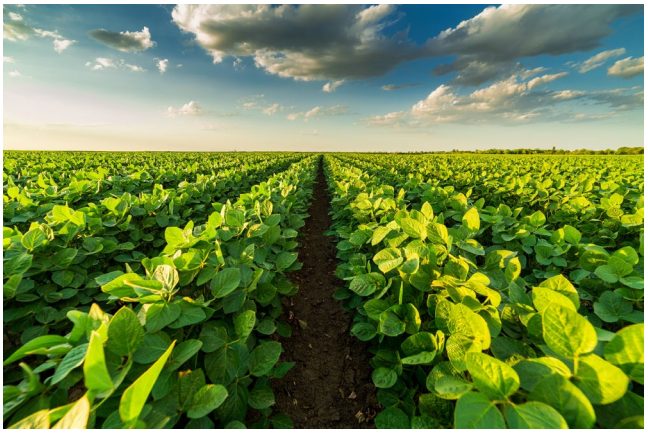
FDA Food Chemical Regulation: Understanding Pesticide Action Levels



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The U.S. Food and Drug Administration's (FDA) March 2025 publication of its new "Chemical Contaminants Transparency Tool" spotlighted a lesser-known aspect of FDA's regulation of pesticide residues on food: action levels. Many stakeholders are familiar with the longstanding legal framework under which the U.S. Environmental Protection Agency (EPA) registers pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In the case of pesticides intended for use on food, EPA also sets the maximum amounts of residues of those pesticides (known as "tolerances") that may be legally present in or on food under the Federal Food, Drug, and Cosmetic Act (FFDCA). Yet, FDA's newly published tool is unrelated to its enforcement of these EPA-established tolerances. Instead, the tool focuses on FDA-established "action levels," which represent FDA's limits for residues of pesticides like DDT and chlordane that EPA has banned for decades and for which no FIFRA registrations or FFDCA pesticide tolerances exist.

FDA's pesticide action levels are not new. In fact, they were derived from a much earlier statutory framework, and FDA has not issued any new pesticide action levels for at least three decades. However, FDA's prominent focus on action levels in the newly published tool comes at a time when the Trump Administration's Make American Healthy Again (MAHA) Commission is promising to increase scrutiny over food additives and other chemicals more broadly (see our alert here). This focus may draw new attention to FDA's continued reliance on historic action levels to allow "unavoidable" levels of certain long-canceled pesticides to remain on food.

How Are Pesticide Residues Regulated?

Under the FFDCA, most substances added to food are subject to exclusive FDA review and regulation as food additives. However, the FFDCA expressly excludes residues of pesticide chemicals from FDA's food additive review. FFDCA § 201(s). Instead, EPA is required to establish limits—or tolerances—on the amount of pesticide residues that can remain on raw agricultural commodities or processed food in connection with EPA's registration of pesticides under the FIFRA. FFDCA § 408(b); FIFRA § 2(bb).

Any pesticide registration applicant may petition EPA to establish a tolerance (or an exemption from the requirement for a tolerance) for that pesticide to permit its use on a particular food-related crop. Tolerance petitions must include information about pesticide application rates, measured concentrations of pesticide residues on the food after the pesticide has been applied according to directions on its label, and safety data.

If EPA determines that the proposed use will not leave residues above an established safe level, the Agency will register the pesticide for use on that food product and set the tolerance level by issuing a regulation. EPA's current tolerance levels and exemptions from tolerance are available at 40 C.F.R. Part 180. As the federal agency charged with overseeing the safety of America's food supply, FDA maintains full responsibility for the enforcement of EPA's established tolerances.

How Does FDA Enforce Pesticide Tolerances?

FDA enforces EPA's pesticide residue tolerances through several mechanisms. Under FDA's Pesticide Residue Monitoring Program, for example, the Agency selectively tests a range of imported and domestic commodities for hundreds of different pesticide residues. FDA may also carry out more focused sampling surveys for specific commodities or selected pesticide chemical residues of special interest. In addition, FDA monitors the levels of pesticide chemical residues in foods prepared for consumption in its Total Diet Study, an assessment that monitors contaminants and nutrients in the average U.S. diet.

FDA may take enforcement action against a food commodity containing a pesticide chemical residue if the residue is found at a level above the EPA-established tolerance for that commodity or in a commodity for which EPA has not established a tolerance (or a tolerance exemption) for that particular pesticide-commodity combination.

If the violation is identified in domestic foods, FDA may issue a Warning Letter to the responsible grower and seek other sanctions, including seizure of the food from commerce or an injunction to correct the cause of the violation. Regarding imported food commodities, FDA may also order shipments to be refused entry into U.S. commerce. FDA may also issue an import alert providing for "Detention Without Physical Examination" (or DWPE), which means that FDA will detain all future shipments without further examination unless the importer can overcome the presumption of adulteration. DWPE can be applied to a product or products from specific growers, manufacturers, or shippers, and may also extend to a geographic area or country if the problem is demonstrated to be sufficiently broad-based.

What Is FDA's "Channels of Trade" Policy?

Consistent with the FFDCA—as amended by the Food Quality Protection Act of 1996 (FQPA)—if EPA revokes a pesticide tolerance under the FFDCA, it also cancels the associated FIFRA pesticide registration for that food use. Similarly, if EPA cancels a pesticide registration for use on a food crop, the Agency will cancel the pesticide residue tolerance for the food.

FIFRA provides that EPA may permit the continued sale and use of existing stocks of a canceled pesticide based on a determination that such sale or use will not have unreasonable adverse effects on the environment. In the absence of concerns about associated dietary risks, EPA generally considers how long it will take for treated commodities to pass through the "channels of trade" in determining when to make a tolerance revocation effective.

When EPA takes such actions, food derived from a commodity that was lawfully treated with the now-canceled pesticide may not have cleared the "channels of trade" by the time the revocation or new tolerance level takes effect. FDA would normally deem such food to be adulterated. However, the FQPA also amended the FFDCA to provide that after EPA revokes, suspends, or modifies a pesticide tolerance (or tolerance exemption), food bearing that pesticide residue may continue to be distributed if the residue is

within the former tolerance, if the responsible party can demonstrate to FDA's satisfaction that the residue is present as the result of an application of the pesticide at a time and in a manner that were lawful under FIFRA. FFDCA § 408(l)(5).

Consistent with this provision, FDA established its channels of trade policy in 2005 to outline its general enforcement approach under these circumstances. As described therein, when a tolerance (or tolerance exemption) expires, FDA will generally consider the degradation rate of the pesticide at issue and provide a certain period of time following EPA's action where FDA will apply enforcement discretion to consider that a residue of that pesticide chemical found by FDA in a specific food, that is within the former tolerance, is the result of the lawful application or use of the pesticide chemical on the food.

What Are Pesticide Residue Action Levels?

Before passage of the FQPA in 1996, FDA relied on its existing statutory authority under the FFDCA to allow residues of certain canceled pesticides that were persistent in the environment and considered unavoidable in food and feed. FFDCA § 406. These "action levels" are outlined in FDA's Compliance Policy Guide (CPG) 575.100, which was last updated in March 1995. FDA issued additional guidance on action level compliance in August 2000. FDA issued a draft revision of CPG 575.100 in January 2008. The draft, which remains unfinalized to date, retained the same action levels previously established.

In consultation with EPA, FDA set action levels for residues of canceled pesticides that may indefinitely persist in the environment and could not be avoided with good agricultural or manufacturing practices. In some cases, action levels are associated with pesticides that have been canceled for over 50 years, including aldrin, dieldrin, DDT, and heptachlor. While action levels specify the level below which FDA exercises its discretion not to take enforcement action, they do not authorize the continued use of any unregistered pesticide on a food crop or establish a permissible level of contamination where it is otherwise avoidable. None of FDA's action levels are binding. In any given case, FDA still reserves the right to initiate an enforcement action below the action level or decide not to initiate an enforcement action if the level is exceeded.

FDA's recently published Chemical Contaminants Transparency Tool consolidates all of its longstanding pesticide action levels in a searchable online database, but it does not introduce any new substantive or policy changes. However, stakeholders should remain attentive to the possibility of further FDA activity in this space, particularly as the tool was released to the public just one month after MAHA-aligned advocacy groups began petitioning FDA to, among other things, establish new limits on food that continues to contain pesticide residues in the channels of trade after an EPA tolerance modification.

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