

NOP (National Organic Program) Approvals of Peroxyacetic Acid vs. the FDA-USDA

In 2000 Congress approved the “Organic Foods Production Act” and designated the USDA as the administrator under a uniform policy known as the NOP-National Organic Program. It was the intention of Congress to standardize and nationalize all facets of the organic growing and production aspects of this endeavor. It also mitigated or eliminated the perceived requirement that products, goods or services be approved or “certified” by a myriad of numerous (and often disconnected) network of regional or local organic certifying agencies and groups, i.e. OMRI.

Prior to 2006 peroxyacetic acid (PAA) had been approved by the NOP for use in organic production under 7 CFR 205.601 (a)(6) “Peracetic acid-for use in disinfecting equipment, seed, and asexually propagated planting materials.” Also, PAA was approved under 7 CFR 205.601 (i)(7) “Peracetic acid-for use to control fire blight bacteria.”

Other regulators and persons of interest have questioned the organic use of Peracetic acid, as it is never marketed as a pure product and is composed of several ingredients. It is an equilibrium product created by the blending of acetic acid and hydrogen peroxide, and often contains a stabilizer that is phosphate-based (HEDP). As an equipment sanitizer for either organic or non-organic production the product must be used in accordance with FIFRA (EPA) regulations, and therefore must be listed in the FDA’s list of “sanitizing solutions” in 21 CFR 178.1010(b) prior to the EPA granting this use on a registrant’s label. PAA sanitizing solutions granted prior sanction by the FDA are listed in 21 CFR 178.1010(b) (30) (38) and (45). The resulting ingredients and tolerances are listed in 21 CFR 178.1010(c). PAA, hydrogen peroxide, acetic acid, sulfuric acid, and HEDP are all listed as acceptable. By law and regulations, a sanitizer must 1st be listed in 21 CFR 178.1010 before the EPA can grant approval for this use.

On Monday, September 11, 2006, in the Federal Register (Vol. 71, No. 175, pages 53299-53303) the USDA- NOP published an Amendment to the National List of Allowed and Prohibited Substances. On the Allowed List, 7 CFR 205.605(b) the USDA added peracetic acid “as Ingredient(s) in or on Processed Products Labeled as “Organic””. To wit: “Peracetic acid/Peroxyacetic acid (CAS # 79-21-0)-for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.”

Let us not make subjective assumptions about what the NOP has Listed and Approved:

- (1) The words “wash and/or rinse” precisely says the product may be used in the wash and/or rinse water for organic production. The PAA product, if used in accordance with FDA limitations, does NOT need to be rinsed from the food product by potable water, by virtue of the NOP’s directive that the PAA may be used in the rinse water.

- (2) The use of the product as a sanitizer in 7 CFR 205.601 is reaffirmed. However, by listing this product's use in 7 CFR 206.605 as a DIRECT food contact processing aid, the product's use as a sanitizer for equipment, without a (intervening) potable water rinse for uses in Organic Production, is validated and *expanded*, if used "according to FDA limitations". Thus, one must refer to one of the appropriate references in 21 CFR 178.1010 as the overriding guideline in regards to maximum use levels on equipment (printed on the EPA label). Keep in mind that all the sanitizers listed in 21 CFR 178.1010 may be used as a (non organic) no-rinse sanitizer on food processing equipment, as long as the maximum allowable ceiling tolerances are observed. For Organic Production, by virtue of PAA's new listing in 7 CFR 205.605(b), it becomes a no-rinse sanitizer NOT requiring an "intervening step", such as a water rinse, prior to production start-up. It is incorrect and illogical for one to assume that even though the PAA has direct organic food contact approval, without the requirement of a potable water rinse, that a potable water rinse would be required if the product was used as an equipment sanitizer...where the ultimate subsequent carry-over of the substance into production wash or process water would be far more dilute than a direct process water application.
- (3) The new NOP directive for PAA in 7 CFR 205.605 does not distinguish the peracetic acid's direct use in either fruit/vegetable or meat/poultry processing situations. One must turn to the 21 CFR to find the appropriate *intended use* "according to FDA limitations." 21 CFR 173.315 is the specific CFR citation for the PAA product's use for "washing or rinsing" of fruits and vegetables. Likewise, if the Organic processing facility produces meat or poultry under the NOP program, the correct FDA limitations or guidelines may be found in 21 CFR 173.370. In addition, some suppliers may offer what is known as a "Notification" approval issued by the FDA for one of these particular uses (173.315 or 173.370). This approval *also* qualifies the supplier's product for use in the specific application listed in the Notification Letter from the FDA...if their product is not otherwise in compliance with the 21 CFR citations.
- (4) Some commenter's have said that PAA is still not approved due to the presence of the HEDP stabilizer "because it is an inorganic ingredient" in the formulation. We again refer you to the key phraseology in the NOP listing in 7 CFR 205.605(b) "according to FDA limitations". When turning to the appropriate FDA citations in 21 CFR 173.315 and 21 CFR 173.370, one will see that the FDA and USDA clearly recognize HEDP, H₂O₂ and PAA as part of the formula and the subsequent tolerance limitation for each is clearly listed. By default, HEDP and H₂O₂ are inclusive with the peroxyacetic acid (PAA) formula.

If your specific use requires a certification for compliance of an FDA regulation if your supplier does not meet the regulations, then you should obtain either a Letter

of Certification from your supplier/distributor for that use, or require a Letter of Notification issued by the FDA. To learn more or view samples of FDA Notifications visit:

www.cfsan.fda.gov/~dms/opa-fcn.html

Lastly, in 2003 the US EPA issued a Pesticide Registration Notice (PR 2003-1) that describes how registrants can obtain Environmental Protection Agency (EPA) approval of label uses and language indicating that all ingredients (active and inert) in the pesticide product and all uses of that pesticide meet the criteria defined in the USDA National Organic Program (NOP) Rule. The only label language that is acceptable under this PR Notice are the phrases "For Organic Production" or "For Use In Organic Production". Any US EPA product containing this statement(s) on the front panel of the label have been accepted and approved the EPA as being in full compliance with the NOP Rules established by the USDA.