

Inc., Washington State University Tri-Cities, Northern Canola Growers Association, and Earthjustice on behalf of the Northwest Coalition for Alternatives to Pesticides, the Natural Resources Defense Council and Farmworker Justice Fund. The comments from outside parties are summarized in Unit V. followed by the Agency's response.

The petition requested that 40 CFR 180.380 be amended by extending the tolerances for the combined residues of the fungicide vinclozolin, 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety, in or on succulent beans at 2.0 ppm for two years. The petition also requested that 40 CFR 180.380 be amended by making the tolerances permanent for canola at 1.0 ppm; eggs, milk, and meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.05 ppm; and in the meat, fat, and meat byproducts of poultry at 0.1 ppm.

Several recent regulatory actions by EPA are pertinent to this petition. In the **Federal Register** of July 18, 2000 (65 FR 44453) (FRL-6594-8), EPA established time-limited tolerances at the levels identified in Unit II. for use of vinclozolin on succulent beans, canola, eggs, milk, meat and meat-by products of cattle, goats, hogs, horses, sheep, and poultry. These tolerances were made time-limited because of the need for a developmental neurotoxicity study to determine whether vinclozolin which causes antiandrogenic effects shares a common mode of toxicity with other members of the imide group of the dicarboximide class of fungicides which are considered antiandrogenic and with other compounds outside of this class of fungicides that may also be considered antiandrogenic.

The tolerances established July 18, 2000, were approved taking into consideration BASF's May 31, 2000 request to EPA to amend its vinclozolin registration to cancel uses on onions, raspberries, and ornamental plants immediately and to delete uses on kiwi, chicory, lettuce, and succulent beans over the following four years. See the **Federal Register** notice of September 20, 2000 (65 FR 56894)(FRL-6744-2). As later approved by EPA these use cancellations contained an existing stocks provision which permitted legal use of vinclozolin on succulent beans until September 30, 2005. Id.

Objections to the tolerances established in July, 2000, were filed on behalf of the Natural Resources Defense Council, the Environmental Working Group, the Pineros Campesinos Unidos

del Noroeste, and the Northwest Coalition for Alternatives to Pesticides by Earthjustice Legal Defense Fund. These objections were withdrawn after EPA approved BASF's use cancellation request and EPA agreed to notify the objecting parties if any future requests were made for uses of vinclozolin under an emergency exemption from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, and consider the objecting parties comments on any such request.

Also as part of BASF's May 31, 2000 cancellation request, BASF asked EPA to revoke tolerances permitting vinclozolin residues in cucumbers and peppers. See the **Federal Register** final rule of June 12, 2002 (67 FR 40185)(FRL-6835-6). Earlier, in 1998, BASF had requested that EPA cancel vinclozolin use on strawberries and stonefruit. Id. Consistent with these two actions by BASF, EPA, on June 12, 2002, revoked tolerances for strawberries, stone fruit, cucumbers, and peppers, 67 FR 40185 (June 12, 2002). This present rulemaking further implements September, 2000 cancellation order by extending the vinclozolin succulent bean tolerance through the date as to which use remains legal on succulent beans, September 30, 2005. Extending the succulent bean tolerance in this manner means that vinclozolin which is legally used on succulent beans pursuant to the cancellation order will not render the treated crops adulterated as a matter of law. See 21 U.S.C. 346a(l)(5). In a future action, EPA will be proposing to revoke the tolerances for vinclozolin on onions and raspberries given that those uses are now cancelled.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of the FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for tolerances for the combined residues of vinclozolin, 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety in or on succulent beans at 2.0 ppm; canola at 1.0 ppm; eggs, milk, and the meat, fat and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.05 ppm; and in the meat, fat, and meat byproducts of poultry at 0.1 ppm.

EPA completed a full risk assessment for vinclozolin as part of the July 18, 2000 tolerance action. July 18, 2000 (65 FR 44453). This risk assessment was updated later that year in connection with the release of the Reregistration Eligibility Document (RED) for vinclozolin. U.S. EPA, Reregistration Eligibility Document Vinclozolin (October 2000) (available at <http://www.epa.gov/REDs/2740red.pdf>). In its July 18, 2000 tolerance decision, EPA concluded that the time-limited tolerances met FFDCA section 408's safety standard. (65 FR 44462). Since that time risks from vinclozolin exposure have declined as the strawberry and stone fruit tolerances have been revoked and the last date for legal use on raspberries and onions has passed by almost 2 years. The registration of vinclozolin for use on succulent beans and lettuce will be canceled on July 15, 2004 with the last legal use of existing stocks established as September 30, 2005. At that point, the only remaining uses for vinclozolin will be on belgian endive, canola, and wine grapes. Taking into account the risk assessments done in conjunction with the July 18, 2000 tolerance action and the vinclozolin RED and the reduction in exposure that has occurred as a result of the cancellations of use on strawberries, stone fruit, onions, and raspberries and the tolerance revocations for cucumbers and peppers,