

EPA concludes that extending the succulent bean tolerance until September 30, 2005, and the canola tolerance until November 30, 2008 meets the section 408 safety standard that is, there is a reasonable certainty of no harm to the general public, including infants and children, from aggregate exposure to vinclozolin.

EPA has retained a time limitation on the canola tolerance because a developmental neurotoxicity study assessing anti-androgenic and neuro-endocrine endpoints has not been conducted. Completion of such a DNT study has been delayed both because EPA needs to investigate anti-androgenic and neuro-endocrine endpoints, endpoints not previously examined in DNT studies, and because the results of the DNT study are critical to assessing whether vinclozolin shares a common mechanism of toxicity with other pesticides which may affect androgens. The Agency currently has no guidance for how this modified DNT study should be conducted, and what specific toxicity endpoints should be evaluated to capture anti-androgenic and neuro-endocrine effects. The Agency is currently examining the vinclozolin data base, as well as data for other chemicals which may effect the androgens. This data analysis extends to both data available in-house and in the literature. When this data analysis is complete, it may be necessary to present this information to the Agency's FIFRA Science Advisory Panel (SAP) to gain insight into whether the chemicals share a common mode of action, whether and how they should be considered in a cumulative risk assessment, and how a DNT study can help the Agency understand this common mechanism question. The data analysis, together with the SAP comments, will be useful in designing the required modified DNT study so that all pertinent toxicological endpoints are measured, and the study is properly conducted. Because the DNT study has not been conducted, EPA has retained the additional 10X FQPA safety factor for the protection of infants and children.

IV. Comments

The Agency received five comments summarized below. The Agency's responses are at the conclusion of the comments.

Comment 1. The North Williamette Research and Extension Center (NWR&EC) of Oregon State University expressed support for extending the tolerance for use of vinclozolin on succulent beans for two years. NWR&EC indicated that the additional time is needed in order to fully evaluate the

efficacy of the potential replacement fungicides (fluazinam and BAS 510) in controlling *Sclerotinia sclerotiorum* under conditions of high disease pressure. Additionally, NWR&EC states that the consequences could be disastrous for a currently financially precarious agricultural industry if adequate time is not allowed for large scale testing of alternative fungicides to ensure efficacy comparable to vinclozolin.

Comment 2. Norpac Foods Inc. (NFI) expressed support for extending the tolerance for use on succulent bean for two years. NFI indicated that vinclozolin has been very effective in controlling white mold (*Sclerotinia sp.*) on succulent beans and has significantly reduced the economic impact of the disease upon the industry. NFI believes that extension of the existing tolerance would allow the industry time to pursue alternative control measures that are currently undergoing evaluation.

Comment 3. The Washington State Pest Management Resource Service (WSPMRS) of the Washington State University Tri-Cities expressed support for extending the tolerance for use of vinclozolin on succulent beans, and discussed the economic significance of succulent bean production to the state of Oregon. WSPMRS indicated that while there have been efforts to register alternative fungicides, researchers believe that field data gathered thus far has not been adequate to assure that the proposed replacement fungicides will prove as efficacious as vinclozolin in controlling white and gray mold.

Comment 4. The Northern Canola Growers Association (NCGA) expressed support for making permanent the tolerances for use of vinclozolin on canola. NCGA discussed the economic importance of canola production to North Dakota, and noted that vinclozolin is a critical tool used by canola growers to combat the devastating effects of *Sclerotinia sclerotiorum*.

Comment 5. Earthjustice commented on behalf of the Northwest Coalition for Alternatives to Pesticides, Natural Resources Defense Council, and Farmwork Justice Fund. Earthjustice discussed in detail three concerns. First, Earthjustice expressed concern that vinclozolin is an endocrine-disrupting chemical and a probable human carcinogen. Second, Earthjustice expressed concern that the notice of filing published in the **Federal Register** on March 26, 2003 did not describe the Agency's duty to cancel vinclozolin's tolerances for succulent beans. Earthjustice asserts that EPA should describe its legal obligations with

vinclozolin in the final **Federal Register** notice responding to the registrant's petition. Third, Earthjustice states that EPA should fill data gaps before taking any regulatory action on vinclozolin. Earthjustice further states that the current data gaps are an extension of decades of data gaps, that EPA appears to be giving up on collecting or analyzing the required data, that EPA has failed to collect data on risks to drinking water, and that EPA admits to numerous other data gaps. Earthjustice concludes their comment by stating that EPA should only finalize the proposed tolerances after collecting required data, making the required findings and fully informing the public about the Agency's regulatory duties for vinclozolin.

Agency response to comments 1-3. Considerations related to the beneficial impacts of a pesticide are cognizable under the FFDCA only in very narrow circumstances. See 21 U.S.C. 346a(b)(2)(B). Those circumstances have not been argued to be present here.

Agency response to comment 4. Given the outstanding data, the Agency has decided not to make the vinclozolin tolerances on canola and the associated egg, milk, meat and meat-by-product tolerances permanent but instead has placed a 5 year time limitation on these tolerances. The Agency will reevaluate this issue after the data as identified in the October 2000 Vinclozolin Registration Eligibility Document are received and sufficiently evaluated.

Agency response to comment 5. The Agency agrees with Earthjustice's discussion of the hazard assessment for vinclozolin in that it is an anti-androgen, and a Group C possible human carcinogen, an effect related to its anti-androgenic properties. These effects, however, were fully considered in the risk assessments conducted for the chemical. The Agency also agrees with Earthjustice that additional data are needed to fully characterize vinclozolin's hazard potential. These data were required as part of the October 2000 Vinclozolin Registration Eligibility Document. In order to account for the data deficiencies, the 10X FQPA safety factor was retained for vinclozolin risk assessments. This 10X factor results in a total safety factor of 1000X.

As noted, the major data deficiency for vinclozolin is the modified developmental neurotoxicity (DNT) study in which antiandrogenic and neuroendocrine endpoints must be assessed. The design and execution of this study presents a host of difficult science issues, including how the study can be conducted in a manner to explore common mechanism questions