WRITTEN OBJECTIONS TO VINCLOZOLIN TOLERANCE FOR SNAP BEANS AND CANOLA (DOCKET CONTROL NO. OPP-301015)

Submitted by

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On Behalf Of:

Natural Resources Defense Council
Environmental Working Group
Pineros y Campesinos Unidos del Noroeste
Northwest Coalition for Alternatives to Pesticides

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On behalf of Natural Resources Defense Council ("NRDC"), Environmental Working Group ("EWG"), Pineros y Campesinos Unidos del Noroeste ("PCUN"), and Northwest Coalition for Alternatives to Pesticides ("NCAP"), we hereby submit the following written objections in accordance with 40 C.F.R. §§ 178.20-.37 to the tolerance granted for residues of vinclozolin on snap beans. The objectors will be referred to as NRDC throughout these objections.

SUMMARY

NRDC objects to the tolerance regulation on the following grounds:

(1) Tolerances must be set at levels that are safe, yet given consumption patterns, some women of childbearing years will be exposed to acute risks if they eat snap beans with residues of vinclozolin at the tolerance level;

(2) EPA used percent of crop treated data in its acute dietary risk assessment in violation of the statutory provision allowing use of such data only in assessing chronic, as opposed to acute, risks; and

(3) Even if EPA could use percent of crop treated data in assessing acute risks, it cannot use such data here because the statutory factors for judging the reliability of such data have not been met.

The submitters do <u>not</u> seek an evidentiary hearing. The issues presented are legal issues that can be decided without an evidentiary hearing.

NRDC seeks expedition of EPA's decision on these objections. These objections follow on the heals of the objections initially filed by NRDC three years ago, which EPA failed to decide until the tolerance at issue expired and the objections became moot. EPA's delay is inexcusable and should not be permitted to recur and threaten to deny the objectors their day in court. Moreover, EPA has decided the issues presented in this second set of objections both in its substantive response to the objections and in issuing the new tolerance regulation. For these

reasons, and also because no factual issues are presented, EPA should not need additional time to act on the objections, and NRDC will seriously consider filing an unreasonable delay case or deeming the objections denied, if EPA does not provide a response within 60 days.

RELIEF

In terms of the relief sought, NRDC asks EPA to rescind the tolerances granted for vinclozolin residues on snap beans, canola, and various animal products. EPA should also take immediate action to revoke other tolerances for vinclozolin on foods to the extent necessary to bring tolerances for those substances in line with FQPA standards.

FEE WAIVER

Under 40 C.F.R. § 180.33(i), objections to a tolerance must be accompanied by a filing fee of $3,025. The Administrator may waive or refund such fees when such a waiver or refund will promote the public interest. Id. § 180.33(m). While ordinarily a $1,500 fee must accompany any request for a fee waiver or refund, this fee is not imposed on any person who has no financial interest in the matter at issue. Id.

NRDC seeks a fee waiver for these objections. None of the objectors has any financial interest in this tolerance or this chemical. Instead, they seek to protect the public from the health risks presented by this pesticide. Imposing such a significant fee will deter interested members of the public from pursuing the objection process. Accordingly, waiving the objection fee in this instance will promote the public interest in protecting public health.

THE ADMINISTRATIVE RECORD

In conjunction with this request, NRDC is filing a Freedom of Information Act request, which is attached, seeking production of the administrative record on which EPA's and judicial review of the objections will be based. NRDC seeks expedition of this request to facilitate a prompt decision on the objections. Because EPA's regulations require presentation of the

objections before the administrative record is made available to parties who are not seeking the registration, NRDC may seek leave to file a supplement to their objections upon review of the record.

In addition, NRDC asks that the record on their earlier objections be combined with the record on the renewed objections, although NRDC does not seek production of the earlier record since it has already been produced. Incorporating the earlier record into this one is fully consistent with EPA's response to NRDC's first objections, which promises to take NRDC's concerns into account in acting on the new tolerance petition. Letter from Marcia E. Mulkey, Director Office of Pesticide Programs (May 10, 2000). In NRDC's May 2000 comments on the new tolerance petition, NRDC asked that EPA's file on the prior tolerance for snap beans and our objections to that tolerance be officially combined with this docket, and that the agency alert us if this approach would not be acceptable and if NRDC had to file duplicates of any of the prior-filed documents. The agency did not notify NRDC of any need to file such documents in the pending proceeding, thereby indicating at least a tacit agreement with a combined record.

BACKGROUND

I. STATUTORY FRAMEWORK FOR REGULATING PESTICIDES IN FOOD

Pesticide use is regulated under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136. To be used lawfully in the United States, a pesticide must be registered for a particular use by EPA under FIFRA.

Another statute, the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 321-338, regulates food safety. Under the FFDCA, EPA establishes tolerances that authorize and place legal limits on the presence of pesticide residues on food. 21 U.S.C. § 346a. EPA must ensure that tolerances are set at levels that are "safe," as that term is defined in the statute. Id. Residues of a pesticide on food that exceed the levels permitted under a tolerance or for which

there is no tolerance are deemed unsafe. Id. A commodity containing such unsafe residues is characterized as adulterated and is unlawful under the FFDCA. Id. § 342.

The Food Quality Protection Act ("FQPA"), enacted in August 1996, amended the FFDCA. In particular, FQPA defines the term "safe" and spells out several mandatory determinations that must be made for a tolerance to be granted. Under the FQPA safety standard, EPA can issue a tolerance only if it has determined that:

> there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all dietary exposures and all other exposures for which there is reliable information.

21 U.S.C. § 346a(b)(2)(A)(ii).

In addition to adopting this new overall food safety standard, FQPA responded to evidence that existing food tolerances failed to account for the particular risks presented to children. National Academy of Sciences, Pesticides in the Diets of Infants and Children (1993) ("NAS Report"). More specifically, EPA did not previously assess the particular toxicity of pesticides to infants and children or children's unique exposures to pesticides and the risks presented by them. Id., Executive Summary at 3-7.

Reacting to this alarming evidence that children face inordinate risks from pesticide residues that had previously escaped analysis and regulation, FQPA mandates that, for threshold effects, "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." 21 U.S.C. § 346a(b)(2)(C).[1] EPA may use a different margin of safety

[1] A threshold effect is an effect for which a level may be identified at which the chemical does not cause or contribute to known or anticipated human health effects. H. Rep. No. 104-669, pt. 2, 104th Cong., 2d Sess. at 41 (1996) ("House Report").

only if, based on reliable data, that margin will be safe for infants and children. Id.

FQPA also directs the Administrator to consider other factors, including aggregate exposures to the pesticide chemical at issue from a variety of food and non-food sources, cumulative exposures to pesticide chemicals that have a common mechanism of toxicity, and "whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects." Id. § 346a(b)(2)(D)(v), (vi), (viii).

In addition, FQPA restricts the circumstances in which the agency may assume that not all crops will be treated with a pesticide:

> PERCENT OF FOOD ACTUALLY TREATED
> (f) In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by the Department of Agriculture) only if the Administrator (i) finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue; (ii) finds that the exposure estimate does not understate exposure for any significant subpopulation group; and (iii) finds that, if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Administrator.

21 U.S.C. § 346a(b)(2)(F).

II. THE RISKS PRESENTED BY VINCLOZOLIN

Vinclozolin is a fungicide produced under the trade name Ronilan by BASF Corporation. Prior to 1997, EPA had established tolerances permitting residues of vinclozolin on various fruits and vegetables, including Belgian endive, cucumbers, dried prunes, grapes, grape pumace, kiwifruit, lettuce, onions, bell peppers, plums, prunes, raisins, raspberries, stonefruits, strawberries, and tomatoes. 40 C.F.R. § 180.380. EPA had also registered vinclozolin for use on turf in residential areas, as well as parks, schools, playgrounds, and golf courses.

Vinclozolin has been associated with numerous adverse health effects. Most serious, vinclozolin has been shown to disrupt the endocrine system, which regulates the release of hormones and other substances that control various functions, such as sexual development.

Scientific studies have demonstrated anti-androgen or demasculinizing effects from in utero exposures to vinclozolin. In a lead study by Dr. Earl Gray – an EPA scientist –vinclozolin was fed to rats during critical periods of fetal development and male offspring exhibited reduced anogenital distance, nipple development, and cleft phallus. Other forms of feminized genitalia were observed, including such malformations as vaginal pouches, undescended testicles, and reduced or absent prostate glands. Gray, Ostby & Kelce, "Developmental Effects of an Environmental Antiandrogen: The Fungicide Vinclozolin Alters Sex Differentiation of the Male Rat," 129 Toxicology & Applied Pharmacology 46-52 (1994); 65 Fed. Reg. at 44,456; Agency Supplement to the Vinclozolin Notice of Filing at 3-4 (May 26, 2000).

Several peer-reviewed studies have linked vinclozolin's anti-androgen effects to one of the metabolites produced as vinclozolin degrades. Kelce, Monosson, & Gray, "An Environmental Antiandrogen," 50 Recent Progress in Hormone Research 449 (1995); Wong, Kelce, Sar & Wilson, "Androgen Receptor Antagonist versus Agonist Activities of the Fungicide Vinclozolin Relative to Hydroxyflutamide," 270 Journal of Biological Chemistry 19998 (1995); Kelce, Monosson, Gamcsik, Laws & Gray, "Environmental Hormone Disrupters: Evidence that Vinclozolin Developmental Toxicity is Mediated by Antiandrogenic Metabolites," 126 Toxicology & Applied Pharmacology 276 (1994); 65 Fed. Reg. at 44,460. Based on these and other studies, EPA has concluded that vinclozolin causes anti-androgen or pseudo-hermaphroditism effects. See 65 Fed. Reg. at 44,455-56.

In addition, based on scientific studies, EPA has classified vinclozolin as a probable

human carcinogen. EPA Office of Pesticide Programs List of Chemicals Evaluated for Carcinogenic Potential (Feb. 19, 1997); 65 Fed. Reg. at 44,456.

III. VINCLOZOLIN'S REGULATORY HISTORY

A. Over a Decade of Emergency Exemption Authorizations of Vinclozolin Use on Snap Beans Without a Food Tolerance

Since the late 1970s, Oregon growers became dependent on vinclozolin to control gray and white molds on snap beans. The growers shifted away from pole snap beans, which were harvested with manual labor, to bush snap beans that could be mechanically harvested, but the mechanical harvesting failed to distinguish between beans with and without mold.

When the molds become resistant to common fungicide combinations in the late 1970s, the growers began using vinclozolin under a series of 14 emergency exemptions sought and obtained by the Oregon Department of Agriculture. Prior to the enactment of the FQPA in August 1996, emergency exemptions could be issued for food uses for which there is no tolerance under the FFDCA. See 21 U.S.C. § 346a(l)(6) (requiring tolerances for food uses permitted under emergency exemptions). In other words, EPA could grant emergency exemptions for use of pesticides without determining whether it would be safe for consumers to eat the foods.

When the Oregon Department of Agriculture sought its fifteenth consecutive emergency exemption for the 1997 season, PCUN and NCAP filed comments with EPA objecting to this recurring use of the emergency exemption process for what had become a routine pesticide use. Presumably as a result of these comments, EPA and BASF Corporation abandoned the emergency exemption process and instead pursued a Section 3 registration.

B. The 1997 Registration of Vinclozolin for Use on Snap Beans Without a Food Tolerance

On May 30, 1997, EPA issued a registration for use of vinclozolin on snap beans. Under

a longstanding regulation, EPA cannot issue a FIFRA registration for a food use unless all required food tolerances are in place. 40 C.F.R. § 152.112(g). In clear violation of its own regulation, EPA issued the registration before it had sufficient information to make required food tolerance determinations.

On July 10, 1997, PCUN and NCAP filed a lawsuit challenging EPA's approval of the vinclozolin registration without the required food tolerances being in place. In the lawsuit, PCUN and NCAP sought a preliminary injunction directing EPA to withdraw the registration until the required tolerances had been issued.

Four days after filing of the lawsuit, EPA issued a tolerance for vinclozolin on snap beans, and that tolerance was published in the Federal Register on July 18, 1997. 62 Fed. Reg. 38,464. The issuance of the tolerance ended the procedural violation at the heart of the district court litigation, but became the target of NRDC's first set of objections.

C. The 1997 Vinclozolin Tolerance for Snap Beans

The July 1997 tolerance allowed residues of vinclozolin and its metabolite on snap beans at 2 parts per million (ppm). 62 Fed. Reg. 38,464 (July 18, 1997). The tolerance was set to expire automatically on October 1, 1999. To facilitate the establishment of the snap bean tolerance, BASF voluntarily terminated its registrations for use on tomatoes, grapes, and plums, as well as some turf uses, although not golf course uses.

NRDC filed objections to the vinclozolin tolerance on the grounds that: (1) EPA had failed to apply a tenfold safety factor based on vinclozolin's demonstrated anti-androgen effects and the incomplete data on vinclozolin's effects on developing infants, children, and adolescents; (2) EPA failed to use conservative assumptions concerning exposure; and (3) EPA failed to consider the cumulative effects of aggregate exposures to vinclozolin and two other anti-androgen fungicides that produce the same metabolite. The objections elaborated on EPA's

failure to use conservative exposure assumptions:

> EPA abandoned a conservative assumption that it traditionally uses in estimating dietary exposure to a pesticide: that 100% of a crop that could be treated with a pesticide will, in fact, be treated. NAS, Regulating Pesticides in Food: The Delaney Paradox, at 59 (1987). In the past, EPA has claimed that this assumption leads to a worst-case exposure estimate and injects additional safety factors into its analysis. In its vinclozolin tolerance decision, EPA refined its worst-case scenario by estimating the percentages of certain crops treated with vinclozolin....

Written Objections to Vinclozolin Tolerance for Snap Beans at 11 (Sept. 15, 1997). EPA issued a data call-in requiring BASF to supply percent of crop treated and other data within five years to substantiate EPA's assumptions in setting the tolerance.

In January 1998, EPA made the administrative record publicly available and gave NRDC 60 days to revise its objections and hearing request. On March 31, 1998, NRDC filed a revised hearing request, asserting that: (1) consistent with EPA policy, EPA should have used an additional safety factor because the lead studies demonstrating anti-androgen effects did not demonstrate a no observable adverse effect level or NOAEL, but instead found statistically significant anti-androgen effects at the lowest dose test, producing what is known as a low observable adverse effect level or "LOAEL"; (2) EPA should have used an added safety factor because of incomplete and unreliable data on vinclozolin's post-natal and neuro-behavioral effects; (3) vinclozolin and two other fungicides have similar toxicological and properties and share a common metabolite and thus EPA should have assessed the cumulative effects of their residues; and (4) EPA lacked reliable exposure and residue data.

The revised hearing request explained how EPA conducted its acute dietary exposure assessment:

> An acute dietary exposure assessment matches consumption data and residue data to estimate acute dietary risks. The agency uses actual consumption data. For the residue data, EPA's Tier 1 assessment uses either the tolerance level or high-end anticipated residues from field trials.

Initially, EPA used tolerance levels or high-end residue field data in its acute dietary exposure assessment. AR IV.4 at 85-87. EPA used a 5.5 mg/kg/day dose of concern based on the Gray studies showing reduced ano-genital distance at 3 mg/kg/day and metabolism studies showing that a single-day dose of 5.5 mg/kg/day could result in tissue concentrations comparable to the 3 mg/kg/day dose.

EPA then calculated the margin of exposure, which is a measure of how close the high-end exposure comes to the NOAEL. A margin of exposure near 1 means that the high-end exposure is essentially the reference dose that serves as the NOAEL. Under the standard 100-fold safety factor, the margin of exposure must be greater than 100. When the FQPA tenfold safety factor for children is added, the margin of exposure must be greater than 1000. Because the toxicity and exposure data are incomplete, EPA should have used a margin of exposure of at least a 1000. Moreover, given that the 3 mg/kg/day dose is a LOAEL, not a NOAEL, as discussed above, EPA should have added yet another additional safety factor.

EPA's Tier 1 acute dietary exposure assessments resulted in margins of exposures of less than 50. AR IV.4 at 85-87. If the level of risk in a Tier 1 assessment is too high, as it was here, the agency allows a Tier 3 assessment to be performed, which limits the residue data entries to only the percent of the crop that it estimates will be treated with the pesticide at issue.

In the Tier 3 vinclozolin analysis, BASF used percent of crop treated and percent of imports, where data were available. BASF used data provided by EPA on the percent of particular crops treated with vinclozolin. For example, for beans, BASF used EPA's data showing 10% of the crop will be treated. Accordingly, for 90% of the entries, it entered 0 into its residue database. For the remaining 10% assumed to be treated with vinclozolin, BASF used field residue data. It then convoluted the consumption and residue distribution databases by matching each consumption of a food on which vinclozolin may be used with randomly selected residue distribution data. AR IV.6.

The Tier 3 acute dietary exposure assessment conducted by BASF in 1996 resulted in an unacceptable margin of exposure. AR IV.6. In August 1996, EPA rejected this acute dietary risk assessment because it showed a margin of exposure of 90 at the 99.9^{th} percentile. AR II.8.

BASF then dropped several uses and conducted another acute dietary exposure assessment, excluding those foods . . . . This assessment resulted in a margin of exposure greater than 100. AR IV.7.

Revised Hearing Request at 13-15.

In the revised hearing request, NRDC charged that EPA could not legally use percent of crop treated data for acute risks and that the percent of crop treated data used in the acute dietary exposure assessment failed to reflect regional variations and current usage:

> For example, the assessment used data for vinclozolin use on green beans that assumed that only 10% of the crop would be treated. However, the Agricultural Chemical Usage Vegetables 1996 Summary reports that 81% of the snap bean crops in Oregon are treated with vinclozolin. (Exhibit 14). That survey also reveals that Oregon is second in the nation in snap bean acreage. Id. At a minimum, the 10% crop treated assumption is an unreliable indicator of exposure in Oregon. More likely, EPA's percent of crop treated is outdated even as a nationwide average given the growing use of vinclozolin in recent years. Prior to last year, vinclozolin was used in only those states that had § 18 emergency exemptions. Even without a permanent registration, vinclozolin was used on 81% of the Oregon crop, and 48% of the New York crop. Use of vinclozolin may well increase now that its use is authorized nationwide.

Revised Hearing Request at 15.

By letter dated July 31, 1998, EPA notified NRDC that it had decided to apply a tenfold safety factor to one population segment – women of child-bearing age based on vinclozolin's demonstrated anti-androgen effects in utero, but not to children, despite evidence that anti-androgens can have adverse effects after birth and through adolescence and the lack of data. EPA also abandoned the peer-reviewed anti-androgen scientific studies conducted by EPA researcher, Dr. Earl Gray, and instead accepted the results of an internal BASF study that had not been peer reviewed. In addition, BASF had proposed to delete from its registration uses of vinclozolin on stone fruits and strawberries. 63 Fed. Reg. 40,710 (June 30, 1998).

In response, NRDC continued to object to the lack of a tenfold safety factor for children, to the use of the BASF data instead of the Gray studies, to the use of percent of crop treated data, and to EPA's failure to conduct a cumulative effects analysis. Moreover, NRDC explained:

> These two defects in EPA's analysis point to an over-arching error in this tolerance determination. EPA's charge under the FQPA safety standard is to ensure that tolerances are set at levels that are safe. FQPA defines "safe" as a

> level at which EPA has determined that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue." 21 U.S.C. § 346a(b)(2)(A)(ii). However, EPA has set the tolerance for vinclozolin on snap beans at a level at which a significant portion of the high end consumers in vulnerable age groups, such as women of child-bearing years, would be exposed to unsafe levels of this pesticide. Approximately one in four women of child-bearing age would consume unsafe amounts of vinclozolin on snap beans at the tolerance level given their consumption levels. A tolerance is not safe if consumers would be exposed to unsafe levels of the pesticide at that level. However, based on its belief that snap beans will not, in fact, contain such residues, EPA has set the tolerance at an unsafe level. This approach runs counter to the statutory direction to set tolerances at safe levels.

Letter to Lynn R. Goldman, M.D., Assistant Administrator at 3 (Sept. 9, 1998).

In August 1999, NRDC submitted two expert declarations substantiating the data gaps described in NRDC's objections and subsequent submissions. NRDC complained about EPA's inordinate delay in responding to the objections, withdrew its request for an evidentiary hearing, and asked EPA to decide the objections on an expeditious basis. Letter to EPA (August 20, 1999).

EPA took no further action on NRDC's objections until long after the 1997 tolerance expired on October 1, 1999. On May 10, 2000, EPA denied the objections as moot. However, EPA recognized that the objections continued to have vitality since other vinclozolin tolerances remained in effect and BASF had sought re-establishment of the tolerance on snap beans as well as a new tolerance for canola. 65 Fed. Reg. 21,427 (April 21, 2000).

EPA, therefore, provided a substantive response to the objections and indicated that it would incorporate this response into its upcoming action on BASF's new request for tolerances. Letter from Marcia E. Mulkey, Director Office of Pesticide Programs (May 10, 2000).

First, EPA decided to apply the full tenfold safety factor for children in its acute, intermediate, and chronic risk assessments based on the two expert declarations and scientific literature provided by NRDC on potential vinclozolin effects on neuro-behavioral development

and gaps in the data on such effects. Id., Response to NRDC's Objections to the Vinclozolin Succulent Beans Tolerance at 3.

Second, while there is some evidence that vinclozolin and two other fungicides induce similar toxic effects, EPA would not decide whether the evidence is sufficient to warrant a cumulative effects analysis until sometime in the future, which meant it would not conduct a cumulative analysis of acute risks as part of the upcoming tolerance determination. Id. at 4-5.

Third, EPA rejected the contention that an additional safety factor is necessary because the key studies found a low observable effect level as opposed to a level at which no effects were observed based on an agency re-evaluation of the original study. EPA also pointed to a new study showing decreased prostate weights at lower doses than the no observable adverse effect level used by EPA for the earlier study. Accordingly, EPA shifted its focus to the prostate study for the most sensitive acute effects of in utero exposure to vinclozolin. Id. at 5.

Finally, EPA rejected the contention that it must set tolerances at a level that will result in no adverse effects, given exposure patterns, even if all food has residues at the tolerance level. EPA rejected this contention, pointing to statutory direction to consider aggregate exposure levels, anticipated residues, and percent of crop treated information. Id. at 5-6.

D. The 2000 Vinclozolin Tolerance for Snap Beans and Canola

In April 2000, EPA provided notice of BASF's petition for vinclozolin tolerances for snap beans and canola. 65 Fed. Reg. 21,427 (April 21, 2000). EPA subsequently issued its summary of the toxicity and risk associated with the proposed tolerances.

NRDC filed legal and technical comments on the proposed tolerances. The legal comments asked EPA to consider NRDC's prior comments and objections in acting on the petition, and to officially combine the file on NRDC's first set of objections with the new tolerance petition file. Letter to Mary Waller from Patti Goldman (May 19, 2000).

NRDC's technical comments objected to the use of percent of crop treated data for acute dietary risks: "Acute analysis should not include any averaging of exposures over time, which is essentially what using [percent of crop treated data] does. A pregnant woman, exposed during a critical window of vulnerability during gestation to a serving of treated succulent beans purchased at a local farm market would not be protected by an analysis that accounts for" percent of crop treated. NRDC Comments Prepared by Gina Solomon, M.D., M.P.H., at 3 (June 4, 2000). NRDC also objected to the use of anticipated residues since such data do not account for those people who purchase food near the fields at farmstands or farmers' markets or who produce their own food. Id. NRDC also continued to object to the use of a no effect level for vinclozolin's anti-androgen effects and to EPA's failure to conduct a cumulative effects analysis. Finally, NRDC pointed out that "Several components of the vinclozolin risk assessment revealed risks as much as 10-fold in excess of levels generally considered safe. The elevated risk numbers in the case of short- and intermediate-term risk and the exceedance of the drinking water level of concern are both very worrisome . . . . We are also not convinced that the EPA analysis is sufficiently conservative to protect public health. Finally, on principle, EPA should not ignore or try to explain-away its own risk assessment when that risk assessment demonstrates an elevated risk." Id. at 4.

On July 18, 2000, EPA issued a final regulation establishing tolerances for vinclozolin on snap beans, canola, and animal products with residues from canola in feed, including eggs, milk, meat, fat, and meat byproducts of cattle, goats, hogs, horses, sheep, and poultry. These tolerances will expire on September 30, 2003. 65 Fed. Reg. 44,453 (July 18, 2000). However, the Federal Register notice indicates BASF may phase out food uses, excluding canola and wine grapes, over a five-year period, and that turf uses may become limited to golf courses. EPA

assesses risks based on the new tolerances when added to existing uses and also under the phase-out proposal often finding unacceptable risks with the new tolerances, but acceptable levels of risk under the future scenario. It appears that EPA is issuing the snap bean tolerance with the intention of eliminating that tolerance down the road as part of the proposal to bring risks into line with acceptable levels. Id. at 44,457; Office of Pesticide Programs, Vinclozolin Summary (July 26, 2000).

As previewed in the denial of NRDC's initial set of objections, EPA applied a tenfold safety factor for both children and women of childbearing years, EPA continued to use percent of crop treated data in assessing acute dietary risks and setting the tolerances, EPA used the new prostate endpoint in assessing acute risks, and EPA refrained from making a common mechanism of toxicity determination and thus did not engage in a full cumulative effects analysis.

In assessing acute dietary risks, EPA selected a no observable adverse effect level of 6 mg/kg/day based on decreased prostate weight in male offspring in a developmental toxicity study in rats. EPA concluded that this is the most sensitive indicator of acute anti-androgen developmental toxicity. EPA identified women of childbearing years as the population subgroup of concern because the anti-androgen effects occur in utero. Moreover, EPA applied a margin of exposure of 1000X (the 100-fold margin of safety, plus an additional FQPA 10X safety factor). Accordingly, the acute population adjusted dose is 0.006 mg/kg/day.

EPA used percent of crop treated data and anticipated residues in its acute dietary risk assessment. Office of Pesticide Programs, Overview of the Vinclozolin Risk Assessment at 3 (July 26, 2000); 65 Fed. Reg. at 44,457-58.

EPA concluded that "Acute dietary risk from vinclozolin in food is above the Agency's

level of concern at the 99.9th percentile of exposure," but that it would be below the level of concern under the phase-out plan. Similarly, the acute risk from food plus drinking water is above the agency's level of concern at and above the 99.85th percentile of exposure. In addition, risk to toddlers playing on treated sod is of concern, but will be reduced under mitigation measures being implemented. Office of Pesticide Programs, Vinclozolin Summary at 1-2 (July 26, 2000) & Overview of the Vinclozolin Risk Assessment at 2-4, 6-9 (July 26, 2000); 65 Fed. Reg. at 44,458-59, 44,461. To come within an acceptable level of risk, EPA relied on the future mitigation measures (which include phasing out the snap bean tolerance) and used a lower percentile of the population that can be at risk than established in EPA policies for satisfying the FQPA safety standard.

OBJECTIONS

These objections challenge EPA's failure to set tolerance at "safe" levels as required by statute. More specifically,

> (1) Tolerances must be set at levels that are safe, yet given consumption patterns, some women of childbearing years will be exposed to acute risks if they eat snap beans with residues of vinclozolin at the tolerance level;
>
> (2) EPA used percent of crop treated data in its acute dietary risk assessment in violation of the statutory provision allowing use of such data only in assessing chronic, as opposed to acute, risks; and
>
> (3) Even if EPA could use percent of crop treated data in assessing acute risks, it cannot use such data here because the statutory factors for judging the reliability of such data have not been met.

The objectors do not seek an evidentiary hearing. The objections present legal issues that can be decided without an evidentiary hearing. Moreover, because EPA has already rendered its decision on these objections in their prior form and in conjunction with issuing the challenged tolerances, NRDC seeks expedition of EPA's decision on the renewed objections.

A. Tolerances Must Be Set at Levels That are Safe

Under the FQPA, EPA may establish a tolerance for a pesticide residue on a food "only if the Administrator determines that such tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i). FQPA defines the term "safe" to mean that:

> there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all dietary exposures and all other exposures for which there is reliable information.

Id. § 346a(b)(2)(A)(ii).

The entire tolerance-setting process is designed to identify the residue levels that will not result in adverse health effects. The FQPA divides pesticide effects into two categories: (1) threshold effects, and (2) nonthreshold effects. Threshold effects are those acute or chronic effects "for which the Administrator is able to identify a level at which the residue will not cause" known or anticipated harm to human health. 21 U.S.C. § 346a(b)(2)(B)(i). Conversely, no such level can be identified for nonthreshold effects, such as cancer.

As the FQPA's legislative history explains: "In the case of a threshold effect for a pesticide chemical residue, the Committee expects that a tolerance will provide a 'reasonable certainty of no harm' if the Administrator determines that the aggregate exposure to the pesticide chemical residue will be lower by an ample margin of safety than the level at which the pesticide chemical residue will not cause or contribute to any known or anticipated harm to human health." House Report at 41. The Report further states that an "ample margin of safety" means "a 100-fold safety factor applied to the scientifically determined 'no observable effect' level when data are extrapolated from animal studies," adjusted, where appropriate, by an additional safety factor. Id.

EPA has determined that vinclozolin's anti-androgen effects are threshold effects. In other words, EPA believes that a level can be identified from the scientific studies at which

vinclozolin will not cause anti-androgen effects in male offspring exposed in utero. Once EPA identifies such a no observable adverse effect level, it adjusts that level by an appropriate margin of safety, as discussed above, which produces what is called the reference dose. Thus, the acute reference dose is the level at which EPA has determined the pesticide chemical residue will not cause or contribute to any known or anticipated harm to human health. EPA has set an acute reference dose for vinclozolin based on the fungicide's pseudo-hermaphroditism effects. However, EPA has not set the tolerance to preclude exposures at that level for two reasons.

First, it has relied on BASF's proposed risk mitigation measures, which may eliminate many food and sod uses of vinclozolin over a five-year period. However, the mitigation proposal is nothing more than a proposal at this time. EPA should not be adding new food uses today based on a proposal that may or may not come to fruition. Moreover, one of the food uses that EPA states may be part of the phase out is snap beans. EPA is, therefore, approving a tolerance for snap beans, which leads to exposures above EPA's accepted threshold based, in part, on the proposal to eliminate that very use down the road. The fact that the exposures may be safe tomorrow does not justify approving new tolerances that lead to unsafe exposures today, especially for pesticides that cause birth defects from acute exposures.

Second, rather than set the tolerance at a level that will avoid exposures at or above the reference dose, EPA has used a higher cut-off on the assumption that not all food will be treated and thus not all women of childbearing years will be exposed to residues at the tolerance levels when they eat green beans.

The flaw in this approach is that a one-time exposure to vinclozolin can cause deformities in male offspring. The proper question, therefore, is whether high-end consumers would be at risk if they consume snap beans with residues at the tolerance level.

Indeed, when the NAS committee conducted an assessment of acute dietary risks of aldicarb – another acutely toxic pesticide – it correlated the tolerance (and above-tolerance detections) with high-end consumption of bananas by children in a single sitting to determine whether the child would receive an acutely toxic dose of the pesticide. NAS Report at 289.

EPA did not base the tolerances on a comparable assessment here. Instead, it set the tolerance for snap beans above the level that will not cause or contribute to any known or anticipated harm to human health.

To analyze whether the tolerance for vinclozolin on snap beans is safe for women of childbearing age, we calculated single day exposures using 6,027 reported eating days for women ages 13 through 50. The data are from the U.S. Department of Agriculture's Continuing Survey of Food Intake by Individuals (CSFII) for the years 1994 through 1996, the most recent data available that provide food consumption estimates on a milligram per kilogram body weight basis.[2] An eating day consists of one day of food consumption reported by an individual. Only eating days verified by U.S. Department of Agriculture ("USDA") scientists as accurate were used in the analysis. The 6,027 eating days consist of one to three days of food consumption reported by 3,091 different individuals.

Vinclozolin exposure was first analyzed on single and then on multiple crops. Women of childbearing age reported eating green beans on 354 out of 6,027 possible days, or 5.87% of all eating days. Eighteen women, or 5% of all eaters, reported eating green beans more than once in a single day. For purposes of exposure to vinclozolin, when a person reported eating green beans

[2] EPA uses CSFII data in its own probabilistic risk models for acute dietary risk assessment. See Office of Pesticide Programs, Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern, at 24 (March 16, 2000) ("Choosing a Percentile"). According to EPA, CSFII data "constitute a reliable and representative national sample" of food consumption for the U.S. population. Id. at 13.

more than once on a single day, the total green bean consumption for that day was considered one eating day in the assessment. The reported single day green bean consumption for eaters ranged from 8 to 420 grams. The mean green bean consumption for green bean eaters was 91 grams. The maximum single meal reported was 337 grams, and the maximum single day consumption was 420 grams.

EPA has validated CSFII data and considers the data to be free from "outliers", or data points that represent inaccurate overestimates of single-day food consumption. According to the agency: "All reported high intake values retained in the 1994–1996 CSFII database have been checked by USDA and resolution of adjudication of values outside specific ranges have been accomplished. Thus, the USDA 1994-1996 CSFII database has been properly evaluated and contains accurate and reliable consumption values that OPP will use in assessment of human dietary exposure to pesticide residues." Id. at 19.

Green bean consumption reported in CSFII 1994–1996 for each individual was then matched with the tolerance for vinclozolin of 2 parts per million (ppm) to calculate whether the maximum legal level of vinclozolin exposure is safe according to the standards adopted by EPA for setting tolerances. For acute exposures, EPA interprets "safe" to allow no more than one tenth of one percent of all individuals in the target population to exceed the acute reference dose on an given day. Id. at 4-5. For perspective, this policy would allow 70,000 women of childbearing age to exceed the acute reference dose on any given day and still be considered to meet the standards of safety in the FQPA. For vinclozolin, EPA has established a reference dose for acute effects of 0.006 mg/kg/day (milligrams per kilogram per day). This analysis showed that 0.434% of women of childbearing age would exceed a safe level of exposure, defined as the acute reference dose, on any given day. This exceedance is four times the number that EPA

considers acceptable and represents approximately 300,000 women of childbearing age each day. Stated differently, the margin of exposure at the 99.9th percentile is 667, far less than EPA's acceptable margin of exposure of 1000 for acute exposures to vinclozolin.

This calculation takes into account the fact that most women do not eat green beans on any given day and that only 5.87% of the more than 6,000 eating days used contained reported green bean consumption. When expressed as a percentage of green bean eaters, the number of women exceeding the vinclozolin acute reference dose each day increases dramatically. Of women who eat green beans, 8.19% (29 of 354) would exceed the acute reference dose on any given day.

These numbers show that a significant number of women would be exposed to unsafe levels of vinclozolin under the tolerance. Thus, EPA has not set the tolerance at a level that is "safe," as mandated by the statute.

This violation of the FQPA is far more than a numbers game. The tolerance is the enforceable limit on pesticide residues. Residues of a pesticide that exceed the tolerance are deemed unsafe, and food containing such over-tolerance residues is adulterated and unlawful. 21 U.S.C. §§ 342; 346a. Conversely, food with residues at the tolerance level is legal.

While EPA may have used assumptions that convince it that not all green beans will have residues at the tolerance level, those assumptions provide little solace to the women who consume large quantities of treated green beans with concentrations of vinclozolin at the tolerance level. EPA's approach is analogous to a state that sets the speed limit at 200 miles per hour on the assumption that few people travel at speeds in excess of 70 miles per hour. As the enforceable limit designed to protect consumers from unsafe pesticide residues, the tolerance should, and under the law must, be set at levels that are safe for consumption.

B. Percent of Crop Treated Data Cannot Legally Be Used to Assess Acute Dietary Risks from Vinclozolin

To reduce risks in its acute dietary risk assessment, EPA assumed that not all crops will be treated with vinclozolin. It used nationwide estimates of the percent of snap bean crops that would be treated with the fungicide. While the tolerance determination does not provide the percentages, in the prior tolerance determination, EPA assumed that only 10% of snap beans would be treated based on national use data. For 10% of its data entries, EPA used field residue data. For the other 90%, EPA entered 0 into its residue database. EPA then convoluted the consumption and residue distribution databases by matching each consumption of a food on which vinclozolin may be used with randomly selected residue distribution data. This approach had the effect of undercalculating the number of women who would be exposed to vinclozolin in snap beans by assuming that 90% of the consumption of beans would be benign.

By using percent of crop treated data to assess acute risks, EPA acted directly contrary to the statute. The FQPA provides, in pertinent part:

> PERCENT OF FOOD ACTUALLY TREATED
> (f) In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical . . . .

21 U.S.C. § 346a(b)(2)(F) (emphasis added).

The plain language of this provision authorizes the use of percent of crop treated data in assessing chronic dietary risks, but not in assessing acute risks. Under well-established canons of statutory construction, known as *inclusio unius est exclusio alterius*, the expression of one thing implies the exclusion of the alternative. Or, as explained by Sutherland: "While every word of a statute must be presumed to have been used for a purpose, it is also the case that every word excluded from a statute must be presumed to have been excluded for a purpose." N.

Singer, Sutherland on Statutes & Statutory Construction, § 46.06 (1998 ed.). Moreover, where the statute speaks with clarity to the issue, the agency may not interpret the statute in a manner that is contrary to the statute's language and purpose. Estate of Cowart v. Nicklos Drilling Co., 505 U.S. 469 (1992); Chevron U.S.A., Inc. v. NRDC, 467 U.S. 837 (1984).

The FQPA expressly authorizes EPA to consider percent of crop treated data in assessing chronic risks. By expressly tying this authorization to the assessment of chronic risks, the statute must be read to prohibit the use of such data in assessing acute risks. The express use of the term "chronic dietary risk" implies the exclusion of acute risks. Moreover, where a general statutory provision, such as the authorization to use available information, and a specific statutory provision, such as the above percent of food actually treated provision, could both be applied, "[i]t is a commonplace of statutory construction that the specific governs the general." Morales v. Trans World Airlines, Inc., 504 U.S. 374, 384 (1992). Here, the explicit limitations imposed on the use of percent of crop treated data control, and they do not permit the use of such data in assessing acute risks.

Any alternative reading would lead to an absurd result. In its vinclozolin tolerance determination, EPA contends that the FQPA should be read to impose restrictions on the use of percent of crop treated data in assessing chronic risks but to permit the unbridled use of percent of crop treated data in assessing acute risks. In a seemingly inconsistent argument, EPA tries to justify disregarding this statutory constraint by claiming that new assessment tools have emerged since Congress passed the FQPA. Both of these assertions skirt over the fundamental principle embodied in the statute that averages and percent of crop treated data are an inappropriate basis

for assessing risks from a one-time exposure to the foods actually treated with the pesticide.[3]

EPA's explanation in the vinclozolin tolerance determination is belied by the FQPA's legislative history, which reiterates that percent of crop treated data may be used "when EPA assesses chronic dietary risk," House Report at 44, and by the NAS Report, which provided the foundation for much of the FQPA and which the FQPA's legislative history cites for the principles to guide interpretation of the FQPA's new tolerance-setting provisions. Id. at 43.

The NAS Report explicitly recommended against using percent of crop treated in assessing acute dietary risks. Id. at 317-18. In discussing the possibility that exposure estimates might be adjusted downward based on the percent of a given crop treated with the pesticide, the NAS Report makes clear: "Such adjustments should not be considered in the case of pesticides inducing acute toxic effects, since peak exposures are of importance in this case." Id. at 317. Moreover, the committee emphatically did "not recommend the routine application of adjustments for the percentage of crop treated in estimating dietary exposure to pesticides." Id. at 318.

The NAS Report illustrated this point in its Aldicarb example of appropriate exposure estimations. Because Aldicarb is acutely toxic, the committee eschewed average daily exposures, which it had used to assess exposure to a pesticide with chronic toxic effects: "individual daily intakes are examined in this example because of the acute toxicity of aldicarb." Id. at 270. The Report elaborated:

> Although the average level of individual exposure to pesticide residues in food is an important determinant of chronic toxicity, peak levels of exposure are more

[3] Moreover, EPA is not free to disregard a statutory prohibition on the use of percent of crop treated data because new assessment methods may have emerged. Congress had a reason for imposing this prohibition, as discussed below. The emergence of new assessment methods does not address Congress' reasons for limiting the use of such data to chronic risks.

> relevant for evaluating acute toxicity. Episodes of relatively high exposure occurring in a single day or even during a single meal may be more pertinent for acute risk assessment, depending on the toxic effect of interest.

Id. at 272. In conducting its assessment, EPA focused on the highest concentrations of Aldicarb found in potatoes and bananas and concluded that a child who consumed a potato or banana with those concentrations would be exposed to an acutely toxic level of the pesticide. Id. at 289.

The NAS committee further explained: "Although average daily ingestion is an appropriate measure of exposure for chronic risk assessment, a different approach is required for acute toxic effects caused by short-term exposure to relatively high levels of substances. Assume that the total intake of a particular pesticide in a single day represents a good indicator of whether an acute toxic response will occur." Id. at 293. According to the NAS committee, individual daily intakes should be examined instead of average daily intakes, and the recorded individual daily intakes should be correlated with the data on residues of the pesticide. Id. at 293.

The law of averages is beside the point when one "hot" green bean can cause deformities in male offspring. To ensure that green beans are safe for pregnant women to consume, EPA cannot assume away consumption patterns that would cause adverse effects, if the beans have been treated with vinclozolin. Not only is the principle well-supported in logic, it is also commanded by the FQPA, which authorizes the use of percent of crop treated data in assessing chronic but not acute risks.

C. The Percent of Crop Treated Data Used in the Vinclozolin

Even EPA could use percent of crop treated data in assessing some acute dietary risks (contrary to the plain language of the statute), the data used must be reliable. The FQPA authorizes EPA to use such data only if finds that: (1) "the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such

pesticide chemical residue"; (2) "the exposure estimate does not understate exposure for any significant subpopulation group"; and (3) "if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Administrator." 21 U.S.C. § 346a(b)(2)(F). The legislative history makes clear that the statute "limits use of such information" to situations in which EPA can make the mandated findings. House Report at 44.

These findings are required to use percent of crop treated data in assessing chronic dietary risk. As stated above, the FQPA does not authorize use of percent of crop treated data in assessing acute dietary risks. Even if it did, EPA cannot make the reliability findings required before such data may be used.

The percent of crop treated data for vinclozolin use on snap beans are not reliable for two reasons. First, the existing data pertain to vinclozolin use in 1998 and earlier, yet EPA did not register vinclozolin for use on snap beans until well into 1997. Prior to that time, vinclozolin could be used only in a handful of states under emergency exemptions granted for the particular growing season. While EPA granted such exemptions for many consecutive years in Oregon and New York, such exemptions were sporadic or nonexistent in most other states. Usage in Oregon and New York have been reported steadily since 1992, with rates fluctuating between 36-48% in New York and growing from 80% to 91% in Oregon. U.S. Department of Agriculture, 1998 Agriculture Chemical Use Estimates for Vegetable Crops (July 1999) (http://usda.mannlib.cornell.edu/reports/nassr/other/pcu-bb/). However, no usage was reported in Washington state from 1994 through 1998, but 94% of snap bean crops in Washington were treated in 1992 – a year in which that state obtained an emergency exemption for the use. USDA, Agriculture Chemical Use Estimates for 1992-1998 (above website); 57 Fed. Reg.

54,398, 54,400 (Nov. 18, 1992). Similarly, vinclozolin was used in Wisconsin only in 1994 – a year in which an emergency exemption was issued for that state. USDA, Agriculture Chemical Use Estimates for 1994 (above website); 58 Fed. Reg. 54,348 (Oct. 21, 1993).

Data from before vinclozolin could lawfully be used nationwide are not an accurate and reliable indicator of what usage will be under a nationwide registration. Indeed, in Oregon, usage increased once the registration was issued from 81% to 91%. USDA, Agriculture Chemical Use Estimates for 1996 and 1998. For canola, usage data are virtually non-existent since vinclozolin was not registered for canola and no tolerances existed until the current tolerance determination.

Second and related to the historical use patterns, usage of vinclozolin on snap beans throughout the United States is far from uniform. For 1998, the percent of crop treated nationwide was 22%, while the percentage in Oregon was 91%. USDA, 1998 Agriculture Chemical Use Estimates. For 1996, the nationwide percentage was 21%, while usage in Oregon was 81% and in New York 48%. USDA, 1996 Agriculture Chemical Use Estimates. By estimating percent of crop treated based on national reporting, EPA has underestimated the usage in certain regions. The national data, therefore, are not a reliable indicator of regional dietary exposure.

The NAS committee recognized that adjustments in chronic exposure estimates might be made based on the percent of a crop treated with a pesticide, but it cautioned that such adjustments will be appropriate only "when the percentage of the crop treated is similar in different regions of the country or when the crop is uniformly distributed throughout the country. . . . When these adjustments are used to adjust the national data, they may result in averages that do not account for regional differences in pesticide use. It is therefore important that exposure

estimates that have not been adjusted for acreage treated be presented and that such adjustments be critically examined." NAS Report at 317. Accordingly, the committee did "not recommend the routine application of adjustments for the percentage of the crop treated in estimating dietary exposure to pesticides. Adjustments for acreage treated are appropriate only under certain conditions. For example, such adjustments may be used when there is little regional variation in acreage treated, or when the crop is uniformly distributed at the national level." Id. at 318.

The percent of crop treated data used in the acute dietary exposure assessment underestimated exposure for various geographic areas and current usage patterns. In these circumstances, and because of the statutory prohibition, the percent of crop treated data cannot be used in the acute dietary exposure assessment.

CONCLUSION

For these reasons, EPA should rescind the tolerances granted for vinclozolin residues on snap beans, canola, and various animal products and take immediate action to revoke other tolerances for vinclozolin on foods to the extent necessary to bring tolerances for those substances in line with FQPA standards.

Respectfully submitted,

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