



United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508C)

EPA 738-R-05-005
July 13, 2006

Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment and Risk Management Decision (TRED) for Sodium Cyanide

***Report of the Food Quality Protection Act (FQPA) Tolerance
Reassessment and Risk Management Decision (TRED) for
Sodium Cyanide***

Approved By:

Debra Edwards, Ph.D.
Director, Special Review and
Reregistration Division

Date

Abstract

This document presents EPA's decision regarding the tolerance reassessment of the registered uses of sodium cyanide. The Agency has determined that there is a reasonable certainty that no harm to any population subgroup will result from exposure to sodium cyanide. Therefore, the one tolerance established for residues of the insecticide hydrogen cyanide as a result of application of sodium cyanide is now considered reassessed as safe under section 408(q) of the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA). EPA issued a Reregistration Eligibility Decision (RED) for Sodium Cyanide in September 1994.

As an insecticide, sodium cyanide is used in California as a source of hydrocyanic gas for quarantine fumigation of surface pests on citrus bound for Arizona. Sodium cyanide is also used in mining, metal finishing and organic chemical industries. For this reason, the Agency also evaluated potential exposure and risk from cyanide in drinking water sources in Arizona.

This TRED addresses the FQPA requirement for reassessment of the tolerance for hydrogen cyanide and provides an assessment of worker exposure associated with the use of sodium cyanide as a source of hydrocyanic gas for fumigation of surface pests on citrus. Although a TRED typically does not include an occupational assessment, this document addresses occupational exposures that were not addressed in the September 1994 RED.

The Agency is issuing this TRED document for sodium cyanide as announced in a Notice of Availability published in the *Federal Register*. The Agency is providing a 60-day period for stakeholders to comment on the risk assessment and respond to this risk management decision. If substantive information is received during the comment period that indicates a need to reconsider the decisions presented in this document, EPA may modify these decisions as appropriate through an amendment.

I. Introduction

This is the Environmental Protection Agency's (hereafter referred to as EPA or the

Agency) “Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment and Risk Management Decision for Sodium Cyanide.” This document is also known as a Tolerance Reassessment Eligibility Decision, or TRED. EPA issued a Reregistration Eligibility Decision (RED) in 1994. This TRED reassesses the tolerance associated with sodium cyanide to ensure the pesticide meets the standards of FQPA.

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, requires EPA to reassess all the tolerances for registered chemicals in effect on the day before enactment of the FQPA on August 3, 1996. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. When a safety finding has been made that aggregate risks are not of concern, and that there is no common mechanism of toxicity with other pesticides, the tolerances are considered reassessed. The existing tolerance associated with sodium cyanide must be reassessed in accordance with FFDCA, as amended by FQPA.

II. Background

Sodium cyanide is not currently registered for any food or feed uses; however, there is one Special Local Needs (SLN) food/feed use registration under Section 24(C) for sodium cyanide. As an insecticide, sodium cyanide is used in California as a source of hydrocyanic gas for quarantine fumigation of surface pests to control red scale on fresh market citrus bound for Arizona. The SLN end-use product is formulated as a granular containing 98% sodium cyanide as the active ingredient. It is applied by professional applicators only. A tolerance for residues of the insecticide hydrogen cyanide which result from post-harvest fumigation as a result of application of sodium cyanide is established at 50 ppm in or on citrus fruit under 40 CFR §180.130. There are no products available for residential application.

The Agency also evaluated the potential exposure and risk from cyanide in drinking water sources in Arizona since it is used for mining, metal finishing, and organic chemical industries. The Agency obtained monitoring data on total cyanide levels in public ground and surface drinking water systems throughout the State of Arizona from the Arizona Department of Environmental Quality (ADEQ). These data and follow-up conversations with State officials indicate that total cyanide concentrations are non-detectable throughout a 13-year period, from January 1993 through June 2006. Based on this information, drinking water exposure is expected to be negligible and was therefore not quantitatively assessed for this TRED.

Sodium cyanide is used as a pre-kill/rodenticide and as an insecticide. As a pre-kill/rodenticide, it is used as a single dose poison in the M-44 ejector device to control animals that prey upon livestock and threatened or endangered species or that are vectors of communicable disease. This product is limited to use only by trained and certified applicators under the direct supervision of a government agency.

This TRED also provides an assessment of and risk management decision for worker exposure associated with the use of sodium cyanide as a source of hydrocyanic gas for fumigation

of surface pests on citrus which was not addressed in the 1994 RED. No additional mitigation measures are required for workers since the Agency's occupational assessment resulted in MOEs that are below the Agency's level of concern.

III. Links to the Sodium Cyanide Assessments

Please refer to the human health and drinking water risk assessments for Sodium Cyanide, dated July 10, 2006 and February 7, 2006, respectively, for details on the risks associated with the use of Sodium Cyanide. These documents are also available in the public docket EPA-HQ-OPP-2006-0352 located on-line in FDMS at <http://www.regulations.gov>.

IV. Regulatory Determinations

A. FQPA Assessment Supporting Tolerance Reassessment Decision

The FFDCA, as amended by FQPA, directs the Agency to use an additional tenfold (10X) safety factor 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. FFDCA authorizes the Agency to modify the tenfold safety factor only if reliable data demonstrates that the resulting level of exposure would be safe for infants and children.

An uncertainty factor (UF) of 100 was applied to the acute RfD based on application of a 10X for intraspecies variation, and 10X for lack of a LOAEL, steep-dose-response curve, and severity of toxic effect. The conventional UF of 10X for interspecies extrapolation was not applied because the endpoint selected for the risk assessment was from a human study.

The Agency concluded that no FQPA Safety Factor is necessary to protect the safety of infants and children in assessing sodium cyanide exposure and risks because there was no quantitative increased susceptibility in postnatal offspring toxicity and there is a low degree of concern for residual uncertainties for pre and/or post-natal susceptibility.

There are no residual uncertainties identified in the exposure databases and the Agency's conservative assessments will not underestimate the potential exposure to infants and children resulting from the use of sodium cyanide. Therefore, the FQPA Safety Factor is 1X for the hydrogen cyanide risk assessment.

EPA has evaluated the dietary, drinking water, residential, and occupational risks from the supported registered uses of sodium cyanide and has determined that there is a reasonable certainty that no harm to any population subgroup will result from exposure to sodium cyanide. The acute dietary exposure estimates for food for the U.S. population and all population subgroups are <100 % of the acute Population Adjusted Dose (aPAD) and are below the Agency's level of concern at the 99.9th percentile of exposure. The highest estimated exposure was to children 1-2 years old at 37% of the aPAD. A chronic dietary exposure assessment was not performed since cyanide is extremely acutely toxic at doses lower than those at which chronic toxicity occurs. Therefore, the tolerance for hydrogen cyanide established at 40 CFR §180.300 is now considered reassessed

under Section 408 (q) of FFDCA.

EPA has determined that risk from exposure to sodium cyanide is within its own “risk cup.” In other words, EPA is able to conclude that the tolerance residues of the insecticide hydrogen cyanide from post-harvest fumigation as a result of application of sodium cyanide meets the FQPA safety standards. In reaching this determination, the Agency has considered the available information on the potential sensitivity of infants and children, as well as potential aggregate exposure and risk. Because there are no residential uses and exposure through drinking water is negligible, aggregate exposure is equal to exposure through food.

B. Cumulative Assessment

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to hydrogen cyanide and any other substances, and, hydrogen cyanide does not appear to produce a toxic metabolite produced by other substances which have tolerances in the U.S. For the purposes of this tolerance reassessment action, therefore, EPA has not assumed that hydrogen cyanide has a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA’s website at <http://www.epa.gov/pesticides/cumulative/>.

C. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.” Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

In the available toxicity studies on hydrogen cyanide, there was no estrogen or androgen, mediated toxicity. Thyroid effects in the presence of liver toxicity were seen in both sexes at the highest dose tested in the chronic dog study. When additional appropriate screening and/or testing protocols being considered under the Agency’s EDSP have been developed, hydrogen cyanide may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

D. Tolerance Reassessment Summary

The tolerance for residues of hydrogen cyanide in/on plant commodities that is currently established under 40 CFR §180.130 is summarized below. The tolerance is expressed in terms of hydrogen cyanide *per se*.

Tolerance Reassessment Summary for Hydrogen Cyanide			
Commodity	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comment/Correct Commodity Definition
Tolerances listed under 40 CFR §180.130			
Fruit, citrus	50	50	Fruit, citrus, group 10

Codex Harmonization

Use of sodium cyanide as a fumigant is limited to citrus treated in California bound for Arizona and not for export. Codex maximum residue limits (MRLs) do not currently exist for hydrogen cyanide.

V. Data Requirements

Residue Chemistry Data Requirements

The required data for the Sodium Cyanide TRED are as follows:

- 860.1380 – Storage stability data for citrus
- 860.1650 – Analytical standards for sodium and hydrogen cyanide are not currently available in the National Pesticide Standards Repository. Analytical Reference standards of sodium and hydrogen cyanide must be supplied and supplies replenished as requested by the Repository.
- 860.1500 – Crop Field Trial Residue data from two additional studies are required along with residue data on whole oranges. A detailed explanation of the modifications to EPA’s analytical report number 335.2 along with validation of this method at the reported LOD of 0.01 ppm is required.

Product Chemistry Data Requirements

- 830.7050 – Ultraviolet/visible Absorption