

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-30000/60A; FRL-5352-6]

### Cyanazine; Notice of Preliminary Determination to Terminate Special Review; Notice of Receipt of Requests for Voluntary Cancellation

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of Preliminary Determination to Terminate Special Review; Announcement of Receipt of Voluntary Cancellation.

**SUMMARY:** This Notice sets forth EPA's preliminary determination to terminate the Special Review of cyanazine based on amendments to the terms and conditions of cyanazine registrations. In effect, the terms and conditions call for an incremental phaseout and voluntary cancellation of all pesticide products containing cyanazine that are registered for use in the United States. The Agency has concluded that, based on these terms and conditions of the amended registration of cyanazine, any unreasonable adverse effects posed by cyanazine use will be eliminated by the phaseout and voluntary cancellation of the chemical. The Agency concludes that the benefits of use of the chemical for the limited period of time and in strict accordance with all of the terms and conditions of registration, outweigh the risks. In making this determination, the Agency considered the risks and benefits of cyanazine use in the 7-year phaseout, during which maximum label rates will be reduced and closed cab application equipment will be required, as well as the risks and benefits associated with the ultimate cancellation of all use of cyanazine. In addition, pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), this Notice announces EPA's receipt of requests to voluntarily cancel all registrations containing cyanazine, effective December 31, 1999.

**DATES:** Comments, data and information relevant to the Agency's proposed decision must be received on or before April 1, 1996.

**ADDRESS:** Submit three copies of written comments bearing the document number [30000/60A]. By mail to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to Room 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, Telephone: 703-305-5805.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number "OPP-30000/60A." No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this document may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit IX. of this document.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the Virginia address given above from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:** By mail: Joseph E. Bailey, Review Manager, Special Review and Reregistration Division (7508W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Special Review Branch, 3rd Floor, Crystal Station, 2800 Jefferson Davis Highway, Arlington, VA, Telephone: 703-308-8173, e-mail: bailey.joseph@epamail.epa.gov. For a copy of documents in the public docket, to request information concerning the Special Review, or to request indices to the Special Review public docket, contact the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: 703-305-5805.

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

##### A. Regulatory Background

Cyanazine is the common name for [2-(4-chloro-6-(ethylamino)-s-triazine-2-

yl)amino)-2-methylpropionitrile], an herbicide sold under the tradenames of Bladex and Cynex that is available as a granular or liquid formulation. It is classified as a "Restricted Use Pesticide" based on its reproductive effects and detection in ground and surface water. Cyanazine was first registered by Shell Chemical Company in 1971. Today, DuPont Agricultural Products and Griffin Corporation are the only registrants of technical grade cyanazine. Ciba Plant Protection also has one registered product, a mixture of cyanazine and metalochlor, but submitted a request for voluntary cancellation of this product which was announced in the Federal Register of November 8, 1995 (60 FR 56333) (Ref. 1). A final cancellation order for this product was effective February 8, 1996.

In April 1985, a Special Review of cyanazine was initiated based on studies indicating developmental toxicity in two species after oral administration of the chemical. The Agency was concerned about potential risks to mixer/loaders and applicators exposed to cyanazine. Additional dermal developmental toxicity studies that were submitted to the Agency led to a refinement of the risk estimates. The Special Review was concluded in 1988 by requiring personal protective equipment and revised label language.

The Agency continued to assess ground and surface water monitoring data for cyanazine contamination and, to help address contamination concerns, approved label amendments in 1993 that reduced maximum application rates and required surface water setbacks. These amendments, however, did not ameliorate all of the Agency's risk concerns and on February 8, 1994, a preliminary notification letter was issued to all cyanazine registrants indicating that the Agency was considering initiating a Special Review of cyanazine because of potential cancer risks from dietary (food and drinking water) and non-dietary exposure. Additionally, the Agency was also concerned about possible ecological risks to nontarget organisms (aquatic organisms, terrestrial plants) and their ecosystems that may result from the use of cyanazine.

On November 10, 1994, EPA issued the Notice of Initiation of Special Review (Position Document 1 or PD 1) formally announcing that a Special Review was being initiated for cyanazine, along with atrazine and simazine (58 FR 60412) (Ref. 2). The Agency formally initiated the Special Review based only on the cancer risk concern to humans. The Agency remains concerned about possible

ecological effects; however, these effects were not considered as formal criteria to initiate the Special Review.

On August 2, 1995, DuPont voluntarily proposed to amend its cyanazine registrations to effectively phaseout the production of cyanazine for use in the U.S. by the end of 1999, with incremental reductions in maximum label application rates in 1997, 1998, and 1999 and a closed cab requirement for applicators beginning in 1998 (Ref. 3). Cyanazine products that have been released for shipment by a registrant on or before December 31, 1999, may only be distributed and sold in the channels of trade in accordance with their labels through September 30, 2002. Such products may only be used through December 31, 2002. EPA accepted DuPont's proposal to amend its cyanazine registrations. Since the acceptance of DuPont's proposal to amend cyanazine registrations, EPA has granted new conditional cyanazine registrations to Griffin based on Griffin's agreement to accept the same terms and conditions as part of its cyanazine registrations (Refs. 4, 5, 6, 7, and 8).

The Agency has evaluated the risks and benefits posed by the terms and conditions of the phaseout and voluntary cancellations submitted by the manufacturers of cyanazine and approved by EPA. Among the factors considered were the risks of use during and after the phaseout period and arising from use of existing stocks, the benefits that will accrue from use during the phaseout and use of existing stocks, the incentives for and likelihood of the development of alternative control strategies of a phaseout as opposed to an immediate commencement of cancellation proceedings, and the litigative risks and uncertainties attendant to a contested regulatory action as opposed to a voluntary action. Taking all of these factors into consideration, the Agency has concluded that risks associated with the proposed voluntary phaseout and cancellation are outweighed by its benefits. Accordingly, the Agency believes the Special Review of cyanazine may be terminated on the basis of the voluntary cancellation.

In response to the triazine PD 1 issued in November 1994, the Agency received a number of comments about the risks and benefits of cyanazine. All of the issues raised in the cyanazine comments received during the comment period are addressed in this Notice and are on file in the triazine public docket (OPP-30000/60). While a number of the comments challenged the Agency's decision to initiate the Special Review of the triazines and questioned various

components of the Agency's assessments, no additional scientific data were received by the Agency that change the Agency's previous conclusions about potential risks from cyanazine exposure. The majority of the comments received were undocumented testimonials that generally made claims concerning the usefulness of cyanazine. A few commenters provided additional ground and surface water monitoring data. All of the comments relating to cyanazine benefits have been considered in assessing the economic impacts of phasing out cyanazine. Similarly, all of the comments relating to cyanazine risks have been considered in assessing the risks associated with the phaseout of cyanazine. Significant comments and the Agency's responses to the comments are discussed in appropriate sections of this Notice. Supporting documentation may be found in the cyanazine public docket (OPP-30000/60).

As discussed above, the Agency has recently granted cyanazine conditional registrations to Griffin Corporation. These recently-approved cyanazine registrations, as well as any others that may be granted by the Agency in the future, are required to comply with all of the same terms and conditions of registration for cyanazine as approved by the Agency for DuPont's registrations. The Griffin products were conditionally registered by the Agency provided that Griffin comply with all of the same terms and conditions of the DuPont cyanazine registrations. If Griffin does not comply with the same terms and conditions of the cyanazine registration, its registrations are subject to cancellation by the Agency in accordance with FIFRA section 6(e). Griffin's release for shipment of its products containing cyanazine constitutes acceptance of the terms and conditions of the registrations. In accordance with FIFRA section 3(c)(7)(A), these conditional registrations have been approved because the Agency has determined that they are substantially similar to other currently registered cyanazine products or differ only in ways that do not significantly increase the risk of unreasonable adverse effects to the environment.

#### *B. Legal Background*

In order to obtain a registration for a pesticide under FIFRA, an applicant must demonstrate that the pesticide satisfies the statutory standard for registration. The standard requires, among other things, that the pesticide will not cause "unreasonable adverse effects on the environment" [FIFRA

section 3(c)(5)]. The term "unreasonable adverse effects on the environment" means "any unreasonable risk to humans or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" [FIFRA section 2(bb)]. This standard requires a finding that the benefits of each use of the pesticide outweigh the risks of such use, when the pesticide is used in compliance with the terms and conditions of registration and in accordance with commonly recognized practices.

The burden of proving that a pesticide satisfies the statutory standard is on the proponents of registration and continues as long as the registration remains in effect. Under FIFRA section 6, the Administrator may cancel the registration of a pesticide or require modification of the terms and conditions of a registration if the Administrator determines that the pesticide product causes unreasonable adverse effects to man or the environment. EPA created the Special Review process to facilitate the identification of pesticide uses that may not satisfy the statutory standard for registration and to provide a public procedure to gather and evaluate information about the risks and benefits of these uses.

A Special Review may be initiated if a pesticide meets or exceeds the risk criteria set out in the regulations at 40 CFR part 154. When EPA believes that a pesticide has met such risk criteria, a notice is published in the Federal Register which announces the initiation of the Special Review. After a PD 1 is issued, registrants and other interested persons are invited to review the data upon which the review is based and to submit data and information to rebut EPA's conclusions by showing that EPA's initial determination was in error, or by showing that use of the pesticide is not likely to result in unreasonable adverse effects on human health or the environment. In addition to submitting rebuttal evidence, commenters may submit relevant information to support EPA's initial conclusions or to aid in the determination of whether the economic, social and environmental benefits of the use of the pesticide outweigh the risks. After reviewing the comments received and other relevant materials obtained during the Special Review process, EPA makes a proposed decision on the future status of registrations of the pesticide.

The Special Review process may be concluded in various ways depending upon the outcome of EPA's risk/benefit assessment. If EPA concludes that all of its risk concerns have been adequately

rebutted, the pesticide registration will be maintained unchanged. If, however, all risk concerns are not rebutted, then EPA will proceed to assess risks and benefits. EPA considers possible changes to the terms and conditions of registration that can reduce risks to a level that satisfies the risk criteria used to initiate Special Review. If risks can be reduced to the level, then the Agency considers whether the benefits outweigh those risks. Based upon this analysis, it may require that such changes be made in the terms and conditions of the registration. Alternatively, EPA may determine that no changes in the terms and conditions of a registration will adequately assure that use of the pesticide will not cause any unreasonable adverse effects. If EPA makes such a determination, it may seek cancellation, suspension, or change in classification of the pesticide's registration. This determination would be set forth in a Notice of Final Determination issued in accordance with 40 CFR 154.33.

When the Administrator proposes to cancel, deny, or change the classification of the registration of a pesticide product which is the subject of a Special Review, regulations at 40 CFR 154.31(b) require that the Agency submit notices of preliminary determination to the Secretary of Agriculture and the Scientific Advisory Panel for review and comment. In the case of the proposed decision for cyanazine, the Agency does not deem this necessary because the cancellation of all cyanazine products is a voluntary action on behalf of the registrants.

Issuance of this Notice means that the Agency has assessed the potential adverse effects of cyanazine and has preliminarily determined that continued, but limited, use of the pesticide under the agreed-upon terms and conditions of cyanazine registration with DuPont and Griffin will not present unreasonable adverse effects when considering: (1) Risks and benefits of restricted, continued use of cyanazine through the phaseout period and (2) the ultimate cancellation of all cyanazine registrations. The Agency is proposing to terminate the Special Review of cyanazine based on the fact that use will be restricted during the phaseout period and no cyanazine use will be allowed after December 31, 2002, and, therefore, continuation of the Special Review is no longer necessary. Included as part of the terms and conditions of cyanazine registration are cyanazine registrants' waivers of rights to challenge the Agency's final action on the cyanazine Special Review or the terms and conditions of registration, including

label amendments, required by agreements in any court or administrative forum. The complete terms and conditions that amend cyanazine registration are provided in Unit X. of this Notice.

## II. Summary of Toxicological Concerns

### A. Carcinogenicity

The initiation of the Special Review of cyanazine in 1994 was based on evidence that cyanazine may cause cancer in persons exposed to the chemical through their diet (food and drinking water) and through exposure while handling the chemical (mixer/loaders and applicators). This risk concern is based on a statistically-significant incidence of malignant mammary gland tumors in female Sprague-Dawley rats that were exposed to cyanazine through their diet for 2 years. In addition to the mammary gland tumors observed in these rats, the weight-of-the-evidence for the carcinogenic potential of cyanazine includes the evidence that cyanazine is structurally related to the other chloro-s-triazines which also induce mammary gland cancer in female Sprague-Dawley rats. Although cyanazine is structurally related to the other chloro-s-triazines, cyanazine differs in that it contains a cyano (nitrile) functional group that is highly reactive.

In March 1991, the OPP Carcinogenicity Peer Review Committee evaluated the weight-of-the-evidence for cyanazine, with particular emphasis on its carcinogenic potential. The Peer Review Committee concluded that cyanazine should be classified as a Group C, possible human carcinogen, and recommended quantification of human risk using a linearized multi-stage model to extrapolate from effects seen at high doses in laboratory studies to predict tumor response at low doses. Using this model, the cancer potency equivalent ( $Q_1^*$ ) for cyanazine is  $1.0 \times 10^0$  (mg/kg/day)<sup>-1</sup> based on the development of mammary gland adenocarcinomas and carcinosarcomas in female rats. This represents the 95 percent upper confidence limit of tumor induction likely to occur from a unit dose. The cancer classification of cyanazine has not been presented to the FIFRA Scientific Advisory Panel (SAP) for review.

A more detailed discussion about the evidence that cyanazine may cause cancer can be found in the PD 1.

### B. Comments Regarding the Carcinogenicity of Cyanazine and the Agency's Response

*Comment:* DuPont Agricultural Products and Griffin Corporation responded that the Agency does not have sufficient toxicological evidence to support its position that cyanazine may pose a cancer risk to humans. Both state that the Sprague-Dawley rat model is inappropriate and that evidence supports their assertion that cyanazine tumorigenicity is associated with a hormonally-mediated threshold effect. *Agency Response:* In the PD 1 for atrazine, simazine, and cyanazine, the Agency considered all information available at that time to evaluate the carcinogenic potential of the triazines, including the appropriateness of the Sprague-Dawley rat model, the method of quantifying the carcinogenic risk and DuPont's assertion that cyanazine tumorigenicity occurs through a hormonal mechanism. In response to the PD 1, the Agency received additional information with comments submitted for atrazine and simazine that will be reviewed and evaluated in the continuing Special Review of those chemicals. The Agency received no new information, however, to dispute the carcinogenicity classification for cyanazine. Currently, it is the Agency's policy to regulate carcinogens based on risk assessment procedures that utilize the  $Q_1^*$  approach in the absence of data to support the hypothesis of hormonally-mediated threshold responses. On several occasions, DuPont has indicated that they have undertaken research that will attempt to validate a hormonally-mediated mechanism of carcinogenicity; however, the Agency received no information from DuPont that attempts to prove such a mechanism exists.

*Comment:* DuPont does not believe that a link between breast cancer and exposure to cyanazine exists and has stated that reviews of several epidemiology studies on estrogen replacement therapy find no such link. *Agency Response:* When the Agency initiated the Special Review for the triazines, it had not concluded that cyanazine was directly related to an incidence of human breast cancer. Upon review of published literature, the Agency indicated that such tumor development in humans seemed possible and that during the course of the Special Review, further research into epidemiological studies would hopefully provide information to make rational decisions about such cause and effect relationships. The Agency is not in a position at this point to draw any

definitive conclusions about human breast cancer and cyanazine; however, the Agency will continue to consider information throughout the Special Review of the other triazines that may help clarify whether an association exists. Information in published literature support the possibility that some link between breast cancer and the triazine herbicides is possible.

*Comment:* The National Coalition Against the Misuse of Pesticides (NCAMP) provided comments about the triazines in general without reference to cyanazine specifically. NCAMP supports the Agency's Special Review of the triazines but unequivocally states that the Agency must cancel the triazines due to unreasonable cancer risks.

*Agency Response:* The terms and conditions of DuPont and Griffin cyanazine registrations now provide for voluntary cancellation of all cyanazine registrations in 1999 and will eventually result in a total phaseout of the use of cyanazine in the U.S. During the period of the phaseout, the Agency estimates that the risks will be decreasing because of the reductions in allowable maximum application rates and the requirement that applicators must work in closed cabs. Taking the cyanazine phaseout and voluntary cancellation into consideration, the Agency has evaluated the risks and benefits of cyanazine and determined that the terms and conditions of the phaseout and voluntary cancellations, as submitted by the manufacturers and approved by EPA, will ultimately eliminate any unreasonable adverse effects associated with the use of cyanazine. Accordingly, the Agency is proposing to terminate the Special Review. As with all Special Reviews, cancellation of uses is an available option but is only imposed

when other less severe risk reduction measures are not adequate to eliminate unreasonable adverse effects.

*Comment:* NCAMP commented that evidence supports the classification of all of the triazines as Group B carcinogens.

*Agency Response:* The Agency has taken its decision about the cancer classification of atrazine and simazine to the SAP on a number of occasions. The SAP agreed with the Agency's cancer classification of atrazine and simazine. Current weight-of-the-evidence for cyanazine supports its classification as a Group C carcinogen. Further, NCAMP did not provide any additional data or evidence to support their assertion. Accordingly, the Agency has concluded that cyanazine is a class C carcinogen. The Agency has not presented the cancer classification of cyanazine to the SAP, and in light of the cyanazine phaseout and the ultimate cancellation of this chemical, does not believe that it is necessary to do so.

*Comment:* In general, Griffin commented that the Agency failed to provide adequate information to allow others to fully evaluate its risk assessments.

*Agency Response:* As required by the regulations governing Special Review procedures, the Agency has provided a record of all background documents used in its assessments through the public docket. The public docket contains all supporting documentation that describes all of the assumptions and values used by the Agency to conduct the risk assessments. The Agency has made available the same level of information for the cyanazine Special Review as it has for other Special Reviews, and this information should be adequate to evaluate the assessments.

### III. Summary of Exposure and Related Human Health Risks

In the PD 1, the Agency provided upper bound estimates of carcinogenic risks from dietary exposure from both food and drinking water and occupational exposure to handlers (mixer/loader/applicators) of cyanazine.

#### A. Dietary Exposure and Associated Risks

Dietary exposure to cyanazine can occur through the direct consumption of cyanazine residues in treated food as well as from commodities that contain secondary residues from animals that were fed cyanazine-treated crops. In the PD 1, the Agency considered all residues (per its equivalency policy), including parent cyanazine and both chloro and hydroxy metabolites, to be of toxicological concern. Anticipated residues were calculated using data from field trials, processing studies, and metabolism studies.

The total upper bound dietary risk estimate from exposure to cyanazine residues in food, as reported in the PD 1, is  $2.9 \times 10^{-5}$ . This estimate did contain a risk contribution from wheat and sorghum, uses which have been voluntarily cancelled and thus removed from cyanazine labels. Removing the risk contribution for wheat and sorghum from the total decreases the total upper bound risk to  $2.7 \times 10^{-5}$ . The Agency has not received any data that justifies the revision of any of the assumptions used in its dietary risk assessment other than the information with respect to the voluntary cancellation of the wheat and sorghum uses. For a detailed discussion of those assumptions, the reader is referred to the PD 1. Table 1 below provides the dietary risk estimates as discussed in the PD 1.

Table 1.—Dietary Cancer Risk Estimates for Cyanazine

Commodity	Anticipated Residue (ppm)	Percent Crop Treated	Exposure (mg/kg/day)	Upper Bound Cancer Risk Estimates
Corn	0.12	20	$1.2 \times 10^{-5}$	$1.2 \times 10^{-5}$
Cottonseed	0.09	5	$9.3 \times 10^{-8}$	$9.3 \times 10^{-8}$
Milk	0.00028 (milk) 0.000034 (non-fat solids)	—	$1.2 \times 10^{-6}$	$1.2 \times 10^{-6}$
Poultry and eggs	0.00232 0.00432 <sup>2</sup>	—	$3.1 \times 10^{-6}$	$3.1 \times 10^{-6}$
Red meat	0.00345 0.0103 <sup>1</sup>	—	$1.0 \times 10^{-5}$	$1.0 \times 10^{-5}$
Sorghum	0.10	5	$1.2 \times 10^{-7}$	$1.2 \times 10^{-7}$
Wheat	0.16	1	$2.3 \times 10^{-6}$	$2.3 \times 10^{-6}$
Total				$2.9 \times 10^{-5}$
Total excluding wheat and sorghum				$2.7 \times 10^{-5}$

<sup>1</sup>Range of values were used for meat, meat byproducts, fat, liver, and kidney.

<sup>2</sup>Range of values were used for meat, meat byproducts, fat, liver, kidney and eggs.

*B. Comments Regarding Cyanazine Dietary Risk Estimates and the Agency's Response*

*Comment:* Griffin contends that Anticipated Residue (AR) values used by EPA were not identified and interpolation of EPA's calculations reveals that values used are exaggerated and inappropriate for determining actual dietary risks. Griffin further objects to the Agency's use of translated data from cattle to estimate anticipated residues in other animal commodities. DuPont disagreed with the extrapolation from metabolism studies to estimate residues in meat, milk, and eggs and the assumption that 100 percent of the livestock feed from corn, cotton, wheat, and sorghum has been treated with cyanazine.

*Agency Response:* The AR values used in the Agency's risk assessment are listed in Table 1 above and were identified in the PD 1 as well as in the supporting documentation that was in the public docket at the time of publication of the PD 1. In completing the dietary risk assessment for cyanazine, the Agency utilized its standard approach to estimate AR values and then used those values in determining dietary exposure estimates and carcinogenic risk through its Dietary Risk Evaluation System (DRES). Documentation supporting the estimation of ARs and dietary exposure values is contained in the references used for the triazine PD 1 and can be found in the triazine public docket. To determine the cyanazine AR values for risk assessment purposes for crop commodities, the Agency averaged the actual residues detected in field trials; for nondetectable residues, the Agency assumed the residue level equalled one-half of the analytical method's limit of detection. This approach precludes the possibility of overestimating or underestimating risks that could otherwise be based on residue values at high or low detections. To estimate the ARs for animal commodities, the Agency used animal dietary burden data which take into consideration anticipated residues on feed crops as well as percent crop treated data and animal metabolism studies. Since the consumption of feed by animals has already been adjusted to account for the percent of the crop that has been treated with cyanazine, use of the 100 percent assumption is appropriate.

The Agency routinely translates data between commodities with sufficient similarities, such as translating apple data to pears. Translation is performed when data are either not available or are insufficient. In the case of cyanazine, crop data do exist. Data for cattle and

other ruminants can be translated only to other animals such as goats, sheep, hogs or horses, but not to poultry. Ruminant data exist for cyanazine and were used to estimate risks in the PD 1. However, at the time the PD 1 was published, cyanazine poultry metabolism data were not available. Therefore, atrazine poultry metabolism data were translated to cyanazine. Since atrazine and cyanazine were grouped for Special Review purposes due to their structural and metabolic similarities, the Agency considered it to be appropriate to bridge this data gap by translation. Griffin did not provide an alternative risk assessment for the Agency to review or any additional data for review and consideration in refining risk estimates. *Comment:* Griffin stated that the Agency's use of information from the 1977 - 1978 National Food Consumption Survey to estimate consumption values is inappropriate because food consumption patterns have changed dramatically over the past 17 years; therefore, ingestion rates used in the dietary risk assessment are invalid. Griffin also stated that the source of the percent crop treated data was not provided.

*Agency Response:* Although Griffin did not agree with the Agency's use of the 1977 - 1978 information to predict ingestion rates, it provided no data that the Agency could use to revise the consumption values. The Agency acknowledges that the 1977 - 1978 National Food Consumption Survey may not reflect the most current consumption profile of individuals in the United States. The continuing surveys of food intake by individuals were performed in 1989 through 1991; the Agency is working to translate these data into a form useful for the Agency's Dietary Risk Evaluation System. However, until these data are in a useable form, the Agency will continue to use the 1977 - 1978 data.

The Agency revised the percent crop treated data for cyanazine in 1994 using the most current United States Department of Agriculture (USDA) and other proprietary usage estimates that were available at that time. The data reflect annual fluctuations in use patterns as well as variability as a consequence of using data from various information sources. Griffin did not supply any percent crop treated data for the Agency to evaluate.

*Comment:* Griffin asserts that EPA calculations incorrectly assume that all secondary sources of ingested cyanazine are contaminated with 100 percent of the AR level.

*Agency Response:* The Agency does use 100 percent of the AR level in its

calculations to estimate dietary risk; however, as discussed above, the AR value has taken factors into consideration to adjust for the fact that 100 percent of a crop may not be treated with the chemical. Therefore, further percent crop treated adjustments are not necessary and would tend to underestimate potential risks.

*Comment:* Griffin purports that EPA provided no specific information about the exposure frequency and exposure duration values used in its calculations; i.e., EPA assumes that an individual consumes a maximum amount of a particular food all in the same day, every day, for an entire lifetime and does not account for differences in exposure duration for people living in urban areas, rural areas and farms.

*Agency Response:* The Agency acknowledges that there are differences in food consumption habits across the U.S. To estimate chronic dietary risk, the Agency considered information it has on the general U.S. population as well as 22 population subgroups. The Agency's Dietary Risk Evaluation System utilizes information that was obtained from the 1977 - 1978 food consumption survey discussed above. This survey was designed to statistically encompass all income levels and all population areas of the U.S., including participants from both rural and urban areas. Average dietary consumption of an individual over a 3-day period is determined. The consumption value is then matched to the self-reported body weight of the individual. All data for both consumers and non-consumers of a particular commodity are then combined or averaged to determine dietary exposure. Currently, this survey provides the best estimate of food consumption patterns in the U.S., assuming average consumption over a 70-year lifetime.

*Comment:* Griffin contends that EPA provided no information indicating the values used for body weight assumptions.

*Agency Response:* Details about the assumptions used in the DRES calculations were provided in the public docket. To calculate dietary risk estimates for food and drinking water consumption, the Agency has used information that was obtained in the 1977 - 1978 food consumption survey. This survey matched individual consumption with individual reported body weights of the respondents and the information is then used by the Dietary Risk Evaluation System to estimate risk. Therefore, the Agency has used the self-reported body weights to calculate both the dietary and drinking water risk estimates. The self-reported body

weights average out to approximately 58 kg.

*Comment:* DuPont states that, because the use of cyanazine on sorghum and wheat was voluntarily canceled, risks from these sources should be removed from the risk assessment calculations.

*Agency Response:* The Agency accepted DuPont's request to voluntarily cancel cyanazine use on wheat and sorghum. The Agency has removed the risk contribution from use on wheat and sorghum from the dietary risk assessment. The upper bound dietary risk estimate without the contribution from wheat and sorghum is  $2.7 \times 10^{-5}$  which is still considered to be unacceptable.

*Comment:* DuPont commented that EPA has presented upper bound risk estimates only and ignored the most likely estimates which would be orders of magnitude lower.

*Agency Response:* It is standard policy for the Agency to provide upper bound carcinogenic risk estimates. The use of less than upper bound risk estimates may not adequately account for risks to the most sensitive populations such as infants, children, or the elderly. The Agency acknowledges that the true risk estimates may be as low as zero for some people in some risk scenarios; i.e. where no exposure is present.

*Comment:* DuPont stated that EPA should not make the assumption that chloro and hydroxy metabolites of cyanazine are as toxic as the parent chemical.

*Agency Response:* In the absence of appropriate toxicological information, it is the Agency's policy to use a default assumption that metabolites are no more or no less toxic than the parent compound. The Agency is not aware of any information that indicates that cyanazine metabolites are less toxic than cyanazine itself. The Agency has

completed its review of the hydroxyatrazine study and is currently determining the study's impact on atrazine and simazine anticipated residue calculations. The Agency has decided that translation of the results of this study to simazine is appropriate. However, because the structure of cyanazine contains the cyano functional group and the other two triazines in Special Review do not, the Agency has decided that it would not be appropriate to translate results of the hydroxyatrazine study to cyanazine.

#### C. Drinking Water Exposure and Associated Risks

Ground and surface water sources provide drinking water for human consumption. While the Agency does not yet have an enforceable regulatory standard or Maximum Contaminant Level (MCL) for cyanazine contamination of drinking water, a lifetime Health Advisory Level (HAL) has been established at 1.0 µg/L. Information from a number of ground and surface water monitoring studies has indicated that cyanazine detections are frequently found, especially in surface waters.

To prepare the PD 1, the Agency considered information from a number of surface water monitoring studies that indicated the presence of cyanazine in areas of the Midwest where it is frequently used. The information from these studies indicates that cyanazine is detected in many streams and rivers for several months post-application at concentrations of at least several µg/L due to runoff. However, the percentage of detections is lower during early spring (pre-application) and during fall and winter, many months after application. Concentrations are usually less than 1.0 µg/L. There are reports of cyanazine detections in some lakes and

reservoirs that remain constant at several µg/L almost year round. The ground and surface water monitoring studies that provide evidence of cyanazine contamination of water supplies are discussed in the PD 1.

The Agency based its drinking water risk concerns on the cyanazine detections discussed above and calculated high end (90th percentile) as well as risk estimates for mean consumption of cyanazine-contaminated drinking water derived from both ground and surface water sources. In the PD 1, the Agency's estimates from exposure to a mean concentration of cyanazine in ground and surface water are  $2.3 \times 10^{-6}$  and  $9.7 \times 10^{-6}$ , respectively. The upper bound risk estimates from a 90th percentile exposure in ground and surface water are  $4.0 \times 10^{-6}$  and  $6.6 \times 10^{-5}$ , respectively. These risk estimates may underestimate the actual risk because they are based on exposure to cyanazine parent compound only and do not include the potential contribution to risk from cyanazine degradates. The Agency is also concerned about exposure to cyanazine degradates that are assumed to be no more or less toxic than the parent compound. It is important to note that the cyanazine drinking water risk estimates are representative values for individuals residing in the corn belt region where the chemical is used and do not apply to the entire U.S. population, particularly areas where the chemical is not used. Details about the Agency's drinking water assessments for ground and surface water may be found in the PD 1. Since the publication of the PD 1, the Agency has not received any information that would significantly alter the cyanazine risk estimates. Table 2 below shows the drinking water risk estimates as provided in the PD 1.

Table 2.—Excess Individual Lifetime Cancer Risk Estimates from Consumption of Cyanazine-Contaminated Surface and Ground Water

	Mean Exposure	90th Percentile
Cyanazine - surface water	$9.7 \times 10^{-6}$	$6.6 \times 10^{-5}$
Cyanazine - ground water	$2.3 \times 10^{-6}$	$4.0 \times 10^{-6}$

#### D. Comments Regarding Cyanazine Drinking Water Risk Estimates and the Agency's Response

*Comment:* DuPont and Griffin contend that data from ground water monitoring programs conclusively demonstrate that cyanazine ground water detections are either nonexistent or extremely low. Neither EPA's modeling nor actual ground water survey data support any

regulatory action to alter cyanazine registration status. DuPont and Griffin specifically noted that studies cited in the PD 1 do not support the claim that ground water contamination with cyanazine is a concern.

*Agency Response:* The Agency continues to believe that cyanazine contamination of ground water supplies poses concerns. Griffin was correct in

stating that cyanazine was not detected in EPA's National Survey of Pesticides in Drinking Water Wells. However, the detection limit in the survey was 2.4 µg/L whereas the Agency's HAL for cyanazine is 1.0 µg/L. It is quite possible that there were undetected residues of cyanazine at or greater than the HAL but less than the detection limit. The fact that cyanazine was detected in few

wells in the Monsanto National Alachlor Well Water Survey is reasonable because the survey focused on the alachlor use area. The Agency does not believe that the use of cyanazine geographically coincides closely enough with the use of alachlor to rely heavily on the results of this study to be representative of the contamination potential of cyanazine. For example, in Illinois, only a small percentage of the total corn acreage is treated with both alachlor and cyanazine. Most alachlor applications are accompanied by treatments with atrazine, dicamba, or glyphosate. Therefore, it would be less likely to detect cyanazine in alachlor use areas. Also, no degradates were analyzed for in the survey. Griffin further stated that no cyanazine was detected in ground water during retrospective studies conducted by Shell. Although the wells were located near fields in which corn had been grown in the last 5 years, in areas where 60 - 69 percent of the wells were tested, cyanazine was not used or usage could not be confirmed in the associated corn field. Therefore, these studies do not represent the most accurate impact of cyanazine use on ground water quality. Cyanazine was detected in 155 of 7,468 wells as noted in EPA's Pesticides in Ground Water Database. The cyanazine detections in the wells of 14 states probably resulted from nonpoint source mechanisms.

The Agency acknowledges that the parent cyanazine compound may not be very persistent under most field conditions; however, total chloro-degradate residues of cyanazine are potentially very persistent depending on environmental conditions such as those that may be found in ground water reservoirs. The Agency also acknowledges that less information is available about the contamination of ground water with cyanazine than with atrazine simply because cyanazine has not been as extensively researched as atrazine. However, the information that the Agency does have about the fate characteristics of cyanazine, the monitoring data, and the large amounts of cyanazine that are used continues to support the Agency's concern for ground water contamination.

*Comment:* DuPont stated that the Agency has no information indicating that cyanazine metabolites will reach ground water in concentrations of toxicological concern.

*Agency Response:* The Agency has limited data on the detection of cyanazine degradates in ground water; however, cyanazine is structurally similar to atrazine and simazine and has similar environmental fate

characteristics with some common degradates. Because of the similarity in fate characteristics, the Agency believes that it is reasonable to assume that cyanazine degradates may reach ground water supplies. Both atrazine and cyanazine degrade to deisopropyl atrazine, a chlorodegradate that the Agency assumes to be no more or less toxic than the parent compound.

*Comment:* Griffin commented that EPA's use of CHEMRANK and LEACH models overestimates cyanazine's leaching potential.

*Agency Response:* The Agency believes that the models used are helpful in judging whether significant differences exist in the leaching potential between different pesticides but are not truly predictive of the amounts of pesticides that will leach to ground water at a particular site. In addition, the screening models used do not take degradates into account; one particular cyanazine degradate, deisopropyl atrazine, is extremely mobile and has been widely found in ground water. So, the models may in fact underestimate risk.

*Comment:* The South Dakota and Minnesota Departments of Agriculture and the Illinois Environmental Protection Agency submitted surface water monitoring data in response to the PD 1 that included information for cyanazine.

*Agency Response:* The Agency has considered the data submitted by each of these commenters. The South Dakota and Minnesota data were consistent with United States Geological Survey (USGS) 1989 and 1990 reconnaissance studies of the Midwestern corn belt that showed levels of cyanazine in the surface waters of those states generally to be substantially lower than in several other states such as Illinois, Iowa and Ohio. Although the available data are not sufficient to conclude with certainty that cyanazine is not a potential problem in either state, the Agency's primary concerns were and remain at this time with some of the other corn belt states. For example, arithmetic average annual cyanazine concentrations for samples collected from West Lake, IA, exceeded the HAL in 1992 and 1993, and for samples collected from Rathbun Reservoir, IA, exceeded the HAL in 1992 and 1994. Although these averages are arithmetic and are only of detects, the Agency believes in this case that the arithmetic averages are relatively close to time-weighted mean concentrations because of the regularity of the sampling dates. Such regularity would not be observed if there were a significant number of non-detects or if the sampling schedule

was skewed. Additionally, the Agency received raw data from the Environmental Working Group in which 29 surface water supplies were monitored for cyanazine biweekly from March, April or May through August 1995. Using these data, the Agency calculated time-weighted mean concentrations. Six of the 29 systems sampled had cyanazine estimated time-weighted mean concentrations greater than the HAL of 1.0 µg/L (Bowling Green, OH - 1.4 µg/L; Columbus, OH - 1.04 µg/L; Danville, IL - 2.47 µg/L; Decatur, IL - 1.88 µg/L; Johnson County, KS - 1.01 µg/L; and Springfield, IL - 3.07 µg/L) (Ref 6).

In response to the PD 1, the Illinois Environmental Protection Agency submitted data to update their network of 30 raw surface water sampling sites from the Moyer and Cross report that covered 1985 - 1988 to include 1989 - 1993. Also provided were data on cyanazine concentrations in finished water samples collected quarterly from September 1992, to June 1994, from numerous surface water source supplies throughout the state. Although the data updating the 30 raw water sampling stations is in summary form with only mean concentrations provided for the entire sampling period (1985 - 1993) given for each site, the reported cyanazine average concentrations equaled or exceeded the HAL at 7 of the 30 sites and equaled or exceeded 3 µg/L at 2 of those sites, even with the damping effect associated with long-term multiple year averaging. Although the arithmetic averages may be somewhat greater than time-weighted mean concentrations, the Agency believes that they are probably not that much greater due to the general collection of samples pre-application and during the fall as well as a small number post-application. The data further support the Agency's position that cyanazine detections in the surface waters of Illinois remain of concern.

*Comment:* Griffin and DuPont commented that detections of cyanazine in surface water fluctuate seasonally with detections peaking in spring and summer but returning to background levels that do not present health concerns for the majority of the year. DuPont believes that studies on effectiveness of best management practices (BMP) provide evidence that DuPont's BMP efforts have helped reduce surface water levels.

*Agency Response:* The Agency agrees that cyanazine detections tend to be seasonal; however, the detections that are reported remain as a concern to the Agency. Monitoring data post 1990 from West Lake and Rathbun Reservoir in

Iowa, as well as data provided to the Agency by the Environmental Working Group and the Illinois Environmental Protection Agency, support the Agency's concern that average annual cyanazine concentrations in some surface source drinking water supplies continue to exceed the HAL of 1 µg/L. Data from studies conducted by Baker in Ohio and the USGS in the Midwestern corn belt show that maximum cyanazine concentrations exceed the HAL and that such concentrations may last several weeks post-application. The Agency agrees with DuPont's statement that concentrations of cyanazine exceeding 10 µg/L are more likely to occur in small streams rather than larger streams and rivers where the concentration is likely to be diluted. DuPont's assertion that small streams do not generally supply drinking water is true. However, cyanazine concentrations often remain elevated for longer periods of time in larger streams and rivers due to cyanazine loadings that occur at different times within the watershed upstream from the sampling location. Also, cyanazine concentrations appear to remain elevated longer in lakes and reservoirs such as West Lake and Rathbun Reservoir due to lower microbiological activities coupled with long hydrological residence times. In the USGS reconnaissance survey of 129 surface water sites within the Midwestern corn belt, greater than 10 percent of the sites had post-application concentrations of cyanazine greater than 10 µg/L; in the study by Baker of eight tributaries of Lake Erie over 4 years (32 site-years), 19 percent had maximum concentrations exceeding 10 µg/L.

The Agency does believe that the changes brought about by the adoption of the BMPs has helped to decrease the triazine loading of surface waters. The Agency believes that the reduction in use rates called for during the phaseout of cyanazine will further help reduce the loading to surface waters from agricultural runoff. However, the decreases observed since the use of BMPs are small and recent data show that cyanazine contamination of some surface water source drinking supplies continues to be a concern.

*Comment:* DuPont disagrees with the Agency's use of a 20 percent Relative Source Contribution (RSC) factor to calculate the HAL and suggests that the Agency revisit this issue before assessing risk based on the current number.

*Agency Response:* The RSC value is a factor that is used to establish regulatory standards for levels of a contaminant in drinking water. The RSC apportions the allowable doses of a contaminant that

are derived from food, water and air. In the case of cyanazine, the Agency has used the default value of 20 percent due to lack of data to support any other value. In other words, the Agency is allowing only 20 percent of the total amount of cyanazine exposure to come from drinking water; the remaining 80 percent can be contributed through other exposure routes such as food and air. In 1994, DuPont requested that the Agency revise the RSC value and modify the cyanazine HAL accordingly. The Agency responded to DuPont's request, concluding that the 20 percent default value for the RSC was appropriate at this time due to uncertainties associated with the contribution of total triazines and their degradates to the total exposure. The Agency has received no additional information that warrants making this change and, therefore, continues to believe that the default value is appropriate. In the PD 1, the Agency's calculations to determine drinking water risk estimates do not use the RSC value or the HAL for cyanazine since actual intake survey data were used to estimate consumption of drinking water and monitoring data were used to estimate exposure to cyanazine. Therefore, changing the RSC value would have no effect on the Agency's drinking water risk estimates.

*Comment:* DuPont disagrees that inclusion of cyanazine metabolites may increase exposure to cyanazine by 10 percent. DuPont submitted data on metabolites in several reservoirs.

*Agency Response:* In the PD 1, the Agency's statement that degradates could increase exposure by 10 percent referred to total triazine degradates in general and did not refer specifically to cyanazine. The study on metabolites in reservoirs, to which DuPont refers, had very high detection limits for major cyanazine degradates; therefore, it is reasonable to conclude that cyanazine degradates were detected in a relatively low percentage of samples. However, in some of the samples where degradates were detected, they were at concentrations comparable to those of parent cyanazine.

*Comment:* DuPont agrees that there are numerous sites where a single measurement or even several measurements may exceed the HAL for cyanazine, yet the annual mean may not exceed the HAL. DuPont states that it is inappropriate to use chronic exposure standards in dealing with exposure from surface waters which are highly variable.

*Agency Response:* The Agency agrees that the concentration of individual surface water samples taken at a given

point in time should not be compared to long-term regulatory standards and has only compared arithmetic and time-weighted annual mean concentrations to the HAL for cyanazine. The Agency has compared some maximum and individual cyanazine concentrations to short-term HALs and to 4 times the HAL. The rationale for comparing maximum or other individual concentrations to 4 times the guidance value is that any single quarterly concentration that is greater than 4 times the guidance value will automatically make the annual average of four successive quarterly samples greater than the guidance value. If this guidance value was actually a regulatory standard, the system would be out of compliance with the Safe Drinking Water Act.

*Comment:* EPA reports that a high percentage of samples from the Chesapeake Bay have triazine detects. DuPont believes such detects should be quantified when assessing risk.

*Agency Response:* The statement in the PD 1 about a percentage of triazine detections in the Chesapeake Bay was intended to support the fact that the triazines are widely distributed in surface waters. The statement was not meant to be interpreted as any measure of risk but rather the far ranging distribution of the triazines in the environment. Also, the statement referred to atrazine only, not cyanazine, and stated that a small percentage of detections were greater than 3 µg/L. *Comment:* DuPont recommends that EPA reconsider appropriate action levels for regulating drinking water contaminants that can occur at varying levels over time. Using an identical exposure level over 70 years of exposure represents excessive conservatism in risk management.

*Agency Response:* Actual exposure data on the same watershed over many years are not available so the Agency cannot conduct assessments as recommended by DuPont. Results using modeling, a possible future option, are currently not sufficiently reliable to use in absolute comparisons to MCLs or MCLGs. In addition, for regulatory purposes, the Safe Drinking Water Act requires the comparison of running annual average concentrations based upon four successive quarterly samples to be compared to the MCL. The Agency acknowledges that the use of water from the same source containing the same contaminant level is conservative since most of the U.S. population moves at some time during their life and does not live in the same area drinking from the same water source for a 70-year lifetime. However, it could be considered as



either an over-estimation or under-estimation depending on the contaminant levels in the other sources of drinking water.

*Comment:* DuPont disagrees with EPA's statement that the concentration of cyanazine in a watershed is proportional to the watershed's size.

*Agency Response:* The Agency did not state that the concentration of cyanazine in a watershed is directly proportional to the watershed size. DuPont has misquoted the statement actually made in the PD 1. The Agency stated that "peak concentrations of triazines are generally greater in surface waters draining small watersheds than in those draining large watersheds. . . ." The statement was intended to be interpreted in the context of discussing watersheds which receive high cyanazine applications. As discussed earlier, smaller streams tend to have higher concentrations than do larger streams and rivers.

*Comment:* DuPont is not aware of any data showing that tile drainage and/or ground water inflow contributes substantially to cyanazine loading of surface waters.

*Agency Response:* Both Moyer and Cross (1990) and Squillace and Engberg (1988) believe that tile drainage and/or ground water inflow sometimes contribute significantly to triazine loadings of surface waters. Because cyanazine has a shorter half-life in surface soil than does atrazine, such contributions are probably substantially smaller for cyanazine than for atrazine.

*Comment:* DuPont commented that EPA indicates that the cumulative effects of various triazines are assumed to be additive. DuPont disagreed stating that information in a study report they submitted in response to the PD 1 entitled "Assessment of the Reproductive and Developmental Toxicity of Pesticide/Fertilizer Mixtures Based on Confirmed Pesticide Contamination in California and Iowa Ground Water," indicates no additive effects and that safety margins in the HAL are more than adequate to protect human health and the environment.

*Agency Response:* Although it is unclear, the Agency assumes that DuPont is referring to additive toxic effects of pesticides as it relates to the Agency's combined risk assessment across several triazines and exposure routes in the PD 1. The study to which DuPont is referring assessed the reproductive and developmental toxicity, not carcinogenicity, of pesticide/fertilizer mixtures based on ground water contamination. The Agency continues to believe that additive effects of exposure to multiple

chemicals may increase risks and will continue to evaluate and revise the combined risk assessment as appropriate through the continuing triazine Special Review. Safety margins built into HALs do not account for additive effects of multiple chemical exposures.

*Comment:* Griffin commented that the exposure values EPA used to characterize daily intake of drinking water are not consistent among the calculations to determine risk from exposure at the HAL, risk from surface water exposure and risk from ground water exposure or with accepted risk assessment methodology.

*Agency Response:* The Agency acknowledges that different body weight assumptions were used in calculating the risk assessment performed for exposure at the HAL (The Agency specified a 70 kg body weight and 2 L/day water consumption value in the PD 1) than were used to calculate risks from ground and surface water consumption. Calculating risk at the HAL is a screening level assessment similar to using tolerance level residues to estimate risk for dietary consumption. The Agency acknowledges that there can be different default assumptions for water consumption; however, the 2L value used to determine the HAL is a traditionally accepted value. However, the Agency provided a refined assessment for the PD 1 that used actual ground and surface water monitoring data and self-reported body weights from the 1977 - 1978 food consumption survey. Use of actual data to estimate risks, as was done in this case, provides a more realistic estimation than does using default assumptions such as exposure at the HAL or an assumed value for body weight.

*Comment:* Griffin stated that EPA has consistently used maximum or high-end values in the drinking water evaluation. The basis for using time-weighted averages is not clear. Actual exposure and risk is doubled because: (1) EPA has not considered surface water treatments that may reduce contamination, (2) it appears that EPA used a body weight of 50 kg in its calculations, and (3) EPA applied an exposure value reflecting tap water only and not commercial beverages. EPA has used maximum values in its drinking water assessment even though cyanazine has actually been detected in few samples.

*Agency Response:* The Agency disagrees with Griffin's statement that maximum or high-end values have been used to estimate exposure in drinking water. The Agency has used time-weighted mean concentrations to provide a better estimate of the exposure to triazine

residues over an extended period of time in order to reduce any over- or underestimation effects that may result from the variability of detection levels at specific sampling times. In estimating exposures in surface waters, time-weighted mean concentrations are generally better approximations of the actual time integrated mean concentration than are arithmetic means whose values tend to be greater due to the general increase in sampling frequency during periods when the highest triazine concentrations are expected.

The Agency has not considered surface water treatment effects on the exposure to cyanazine because it cannot be assumed that all individuals are consuming drinking water that has actually been treated. It cannot be assumed that every household is connected to a public water system that provides adequate treatment to remove possible triazine contamination. Since most water systems employ only primary treatment methods (e.g., solids removal), cyanazine concentration in raw and in finished water should generally be comparable. It is true that the Agency did not include "commercial water" such as that added during the manufacturing and processing of beverages. The survey from which the Agency has taken the drinking water consumption value only included tap water that is consumed directly or that is used in the preparation of foods or beverages in the home.

*Comment:* DuPont submitted a number of studies in response to the PD 1 that provides information about the effects of BMPs on cyanazine movement in the environment.

*Agency Response:* The Agency has not reviewed these studies to prepare this Notice. As discussed earlier, the Agency does not believe that the BMPs that have been put in place have totally addressed the Agency's ground and surface water concerns because of the more recent monitoring data that continue to show detections. These studies will be considered in the continuing Special Review of atrazine and simazine to evaluate the effects of BMPs on herbicide environmental contamination. Even though some of the BMPs may have a positive impact on ground and surface water contamination and potential ecological effects, the risk concerns associated with occupational exposure and dietary exposure from food consumption will remain unchanged.

*Comment:* The Environmental Working Group (EWG) submitted its report "Tap Water Blues" to the Agency in response

to the initiation of the triazine review. EWG also submitted a follow-up report entitled "Weed Killers by the Glass" which indicates cyanazine detections in drinking water samples taken directly from the taps in people's homes or offices.

*Agency Response:* The Agency thinks that the data indicating cyanazine detections in drinking water are significant and support the Agency's risk concerns. As discussed earlier, some of the water systems that were sampled by EWG had time-weighted mean concentrations higher than the cyanazine HAL of 1.0 µg/L. The Agency will fully evaluate the information with respect to atrazine and simazine as part of the continuing Special Review of the triazines.

*Comment:* EWG comments that EPA standards for triazines in food and drinking water are not consistent and allow levels in drinking water that are unsafe and would not be allowed in foods. EWG points out that there is no enforceable standard for cyanazine and recommends promulgation of a combined MCL for the triazines, including metabolites. NCAMP also commented that the Agency's regulation of contaminants in drinking water is less stringent than the regulation of residues in food and that metabolites should be included in all regulatory standards.

*Agency Response:* While the Agency does not have an MCL for combined triazines, including metabolites at this time, it is considering establishing such an enforceable standard. Because cyanazine is being phased out over the

next several years, it is unlikely that the Agency will establish an MCL for cyanazine.

*Comment:* EWG recommends weekly monitoring of drinking water in susceptible regions for all triazines and metabolites during high runoff and vulnerable periods. EWG also recommended that exposure estimates must include recent data from Missouri and other states demonstrating that peak exposures and annual average concentrations for many rural communities far exceed health standards.

*Agency Response:* The Safe Drinking Water Act establishes the requirements for monitoring pollutants in drinking water. The Agency will consider the most recent monitoring data available to estimate triazine exposure in drinking water when the risk estimates are revised for the preliminary determination of the triazine Special Review.

*Comment:* EWG commented that the Agency must concentrate its risk assessment only on exposed populations. Unexposed populations deflate risks faced by people with contaminated water.

*Agency Response:* The Agency acknowledges the value of this comment and, providing that adequate information is available, will respond to this issue in the PD 2/3 for atrazine and simazine.

*E. Occupational Exposure and Associated Risks*

For the PD 1, the Agency determined exposure estimates for cyanazine use on

corn, the predominant use site, for different scenarios depending on whether the person exposed to cyanazine was mixing, loading or applying cyanazine or performing a combination of these tasks.

Additionally, estimates were provided for growers and commercial applicators and whether open or closed equipment is used. Those estimates were based only on dermal exposure assuming a dermal absorption value of 2 percent and a use rate of 3 pounds active ingredient per acre (lb/ai/acre).

Just prior to initiating the triazine Special Review, DuPont provided the Agency with its own occupational risk assessment that estimated exposure to cyanazine by using information in the Pesticide Handlers Exposure Database (PHED) for ground application (Ref. 7). After reviewing DuPont's assessment, the Agency revised its own risk assessment for ground application of cyanazine by using PHED information to estimate worker exposure (Ref. 8). Aerial application risks were not revised and remain as reported in the PD 1. The Agency used a more recent version of PHED (version 1.1) than did DuPont (version 1.01) that contains more data and therefore provides a greater degree of confidence in the exposure estimates. Table 3 below provides the Agency's revised occupational risk estimates as well as DuPont's estimates for groundboom application of cyanazine.

Table 3—Exposure and Risk Estimates for Groundboom Applications of Cyanazine to Corn

	Daily Exposure mg/kg/day	Annual Exposure mg/kg/year	LADE mg/kg/day	Estimated Upper Bound Risk (EPA)	Estimated Risk (Dupont)
<b>Grower</b>					
Mixer/Loader Open	0.0099	0.0109	1.5 x 10 <sup>-5</sup>	1.5 x 10 <sup>-5</sup>	1.71 x 10 <sup>-6</sup>
Applicator Open	0.0044	0.0048	6.5 x 10 <sup>-6</sup>	6.5 x 10 <sup>-6</sup>	5.2 x 10 <sup>-7</sup>
M/L/A Open	0.0143	0.0157	2.2 x 10 <sup>-5</sup>	2.2 x 10 <sup>-5</sup>	2.23 x 10 <sup>-6</sup>
Mixer/Loader Closed	0.0020	0.0022	3.0 x 10 <sup>-6</sup>	3.0 x 10 <sup>-6</sup>	N/A
Applicator Closed	0.0016	0.0018	2.4 x 10 <sup>-6</sup>	2.4 x 10 <sup>-6</sup>	N/A
M/L/A Closed	0.0036	0.0040	5.4 x 10 <sup>-6</sup>	5.4 x 10 <sup>-6</sup>	N/A
<b>Commercial</b>					
Mixer/Loader Open	0.0729	0.0874	1.2 x 10 <sup>-4</sup>	1.2 x 10 <sup>-4</sup>	5.28 x 10 <sup>-5</sup>
Applicator Open	0.0321	0.0385	5.3 x 10 <sup>-5</sup>	5.3 x 10 <sup>-5</sup>	4.64 x 10 <sup>-6</sup>
M/L/A Open	0.1050	0.1259	1.7 x 10 <sup>-4</sup>	1.7 x 10 <sup>-4</sup>	5.75 x 10 <sup>-5</sup>
Mixer/Loader Closed	0.0147	0.0177	2.4 x 10 <sup>-5</sup>	2.4 x 10 <sup>-5</sup>	N/A
Applicator Closed	0.0117	0.0139	1.9 x 10 <sup>-5</sup>	1.9 x 10 <sup>-5</sup>	N/A
M/L/A Closed	0.0264	0.0316	4.3 x 10 <sup>-5</sup>	4.3 x 10 <sup>-5</sup>	N/A

Daily Exposure = lb ai/day X Unit exposure X % Dermal absorption/70  
 Annual Exposure = lb ai/year X Unit exposure X % Dermal absorption/70

LADE = Annual exposure } 365 X 35/70

Risk = LADE X Q\*

Dermal absorption = 2% (DuPont's estimates are based on 1% dermal absorption)

Q\* = 1

### F. Comments Regarding Cyanazine Occupational Exposure Risk Estimates and Agency's Response

*Comment:* Griffin asserts that: (1) EPA has used an application rate of 3 lb/ai/a, but states that 1.5 lb/ai/acre is commonly used for cyanazine, and that using the higher rate is a violation of EPA's legal obligation to base regulatory activities on actual data, (2) EPA used a dermal absorption value of 2 percent to calculate risks, while studies indicate the actual dermal absorption value to be .84 percent, and (3) EPA's risk assessment is overestimated and meaningless because application rates were doubled and the dermal absorption value was exaggerated.

*Agency Response:* The Agency has estimated occupational exposure to cyanazine based on an application rate of 3 pounds per acre when applying cyanazine alone. The Agency noted in its risk assessment that a rate of 1.5 pounds per acre is often used; however, this rate is typically used when cyanazine is applied in combination with another herbicide, often atrazine. While some cyanazine usage occurs at rates greater than 3 lb/ai/acre (up to greater than 5.0 lb/ai/acre) the majority of usage occurs at rates of 3 lb/ai/acre or less. The dermal absorption rate used in the Agency's risk calculation is based on the actual amount absorbed plus the amount remaining bound to the skin after washing as shown in a dermal absorption study. Therefore, the 2 percent value used in the Agency's risk assessment represents the total amount of cyanazine that could potentially be absorbed through the skin. Assuming

that the amount remaining bound to the skin after washing will be absorbed over time is consistent with the Office of Pesticide Programs' risk assessment practices.

*Comment:* DuPont commented that occupational exposure risks were in the acceptable range and referenced their risk assessment submitted to the Agency.

*Agency Response:* After reviewing DuPont's assessment, the Agency revised its occupational risk assessment and then compared the two. In using updated PHED information, the Agency's revised risk estimates were lower than those estimates originally reported in the PD 1; however, the risk estimates are not as low as those estimated in DuPont's assessment. The assumptions that the Agency used in its risk estimates vary from the assumptions used by DuPont. The Agency's unit exposure estimates are based on a newer version of PHED and the Agency has also used a different dermal absorption value than DuPont, as discussed above. The Agency used information from PHED derived from atrazine studies in which application parameters comparable to those for cyanazine were used. DuPont's assessment for applicators is unacceptable due to the lack of sufficient replicates used. Most of the exposure estimates for applicators were based on data representing less than the required minimum of 15 replicates per body part. Further, for some of the exposure scenarios used by DuPont, the risks were higher than negligible and of concern. The Agency has used updated use and usage information to estimate

the number of acres treated for exposure estimations. Therefore, the Agency believes its revised estimates are more accurate than those presented in the PD 1 and those calculated by DuPont.

### G. Combined Cancer Risks Across Multiple Exposure Pathways and Chemicals

In the notice initiating the Special Review of the triazine herbicides, the Agency provided examples of assessments of total risk that was possible to individuals who may be exposed to more than one of the triazines and from more than one exposure pathway. This was the first time that the Agency looked at the additive risks associated with a group of similar pesticide chemicals. In the combined risk assessment, the Agency provided estimates of the total risk from exposure to atrazine, simazine and cyanazine from dietary, drinking water, occupational and residential exposure. In the PD 1, the Agency acknowledged that various total risk estimates were possible depending on the combination of chemicals to which one is exposed and the combination of exposure routes. With the ultimate phaseout of the use of cyanazine, this chemical will eventually cease to contribute to the total combined triazine risk. However, during the phaseout, while cyanazine continues to be used, the Agency will continue to evaluate its contribution to the total risks of the triazine herbicides in Special Review. Table 4 below shows the Agency's upper bound estimates of total cancer risks across several exposure pathways and triazines.

Table 4.—Upper Bound Total Cancer Risks Across Several Exposure Pathways and Triazines

Exposure Pathway	Atrazine	Simazine	Cyanazine <sup>1</sup>	Total
Dietary	$4.4 \times 10^{-5}$	$1.1 \times 10^{-5}$	$2.7 \times 10^{-5}$	$8.2 \times 10^{-5}$
Drinking Water <sup>2</sup>	$4.2 \times 10^{-6}$	$6.2 \times 10^{-7}$	$9.7 \times 10^{-6}$	$1.5 \times 10^{-5}$
Occupational <sup>3,4</sup>	$1.1 \times 10^{-3}$	N/A	N/A	$1.1 \times 10^{-3}$
Residential <sup>5</sup>	$1.1 \times 10^{-4}$	N/A	N/A	$1.1 \times 10^{-4}$
Total	$1.3 \times 10^{-3}$	$1.2 \times 10^{-5}$	$3.7 \times 10^{-5}$	$1.3 \times 10^{-3}$

<sup>1</sup>Risk contribution from use on wheat not included.

<sup>2</sup>Derived from surface water.

<sup>3</sup>Private grower application to corn using ground boom equipment - mixer/loader/applicator.

<sup>4</sup>Application of a combination of atrazine and cyanazine.

<sup>5</sup>Lawn treatment by homeowner using hand cyclone spreader.

### H. Comments Regarding Combined Risk Estimates and Agency's Response

*Comment:* Griffin commented that EPA has failed to recognize that a critical factor to be addressed when combining risks is the compounding of maximum values. For example, if 90th percentile values are used to assess risk for each pathway to be combined, the total risk

actually represents an estimate closer to a 95-99th percentile range, an overexaggeration that reduces the value of the risk estimate for decision making.

*Agency Response:* The Agency acknowledges that a simple additive approach was used in combining the risks for atrazine, simazine, and cyanazine. This approach was deemed

scientifically sound as the estimates were based on the induction of the same tumor type in the same animal strain, quite possibly via the same or similar mode or mechanism of action. The combined risk estimate contains all of the uncertainties of the numbers used in the individual calculations. If all of the triazine risk numbers were roughly of

the same magnitude, then addition of many upper bound numbers could eventually lead to an over-estimate of risk. However, adding upper bounds in this case should not be considered to over-estimate the risk since one chemical or one pathway "drives" the risk. In the case of the triazines, the occupational risk from atrazine of  $1.1 \times 10^{-3}$  is driving the overall risk of  $1.3 \times 10^{-3}$ .

*Comment:* EWG and NCAMP support the Agency's combined risk assessment for the triazines. EWG requests that the Agency calculate the effect of exposure to infants and children on their lifetime cancer risks, the average exposure levels for infants and young children, the degree to which it is disproportionately occurring in early life and the significance of this exposure. NCAMP further urges the Agency to extend that risk assessment concept to include all pesticides with similar toxic endpoints. *Agency Response:* The Agency agrees that it is important to consider the differences between infants, children, and adults when estimating risks and is working to develop scientifically-sound methodologies to account for such differences in sensitivity and/or exposure and their impact on the lifetime cancer risk estimates. Many factors such as the length of exposure and variations in exposure levels need to be considered in the risk assessment process. The triazines Special Review is the first case study for estimating total risks from chemicals which are similar. The Agency will likely apply the principles that are used in the combined risk assessment in the triazine case study to estimate combined risks from other pesticides that have concurrent exposure and/or common mechanisms of toxicity in future risk assessments.

#### IV. Summary of Exposure and Related Ecological Risks

At the time the Agency initiated the Special Review of atrazine, simazine, and cyanazine, it did not include ecological risk as a formal trigger to initiate the review. The Agency did, however, express concerns about the potential risks to aquatic organisms, terrestrial plants and their ecosystems. The Agency based its concern on a number of studies that indicate acute effects on various aquatic organisms and terrestrial plants. These studies were discussed in detail in the PD 1 and the Agency requested any additional information about ecological effects at the time the Notice was published. The Agency did not receive any new information or new studies that either supported or rebutted its concern about potential ecological risks from the use of

the triazines; therefore the Agency has not changed its position regarding the ecological effects. Even though this Notice is proposing the termination of the cyanazine Special Review, the Agency will continue to look at adverse effects on ecological parameters in the continuing Special Review of atrazine and simazine.

#### *Comments Regarding Ecological Risks and Agency's Response*

*Comment:* NCAMP supported the Agency's concerns about potential ecological risks associated with the triazines and cited a number of published studies about the toxic effects on aquatic and terrestrial organisms. *Agency Response:* NCAMP did not provide any information other than citing several studies about the potential ecological risks of the triazines. The Agency conducted a comprehensive literature search and considered all published information in its assessment of triazine ecological risks at the time the triazine PD 1 was issued. The studies that supported the Agency's ecological concerns are discussed in detail in the PD 1. In the PD 1, the Agency stated that exclusion of ecological risks as a Special Review trigger at that time would not preclude the Agency from including those risks in the review at a later time, should additional information warrant it. The Agency will continue to evaluate ecological concerns as the Special Review of atrazine and simazine proceeds. If new information becomes available that changes the Agency's position regarding the ecological risks of atrazine and simazine, the Agency may include them in the Special Review.

#### V. Summary of Qualitative Benefits and Impacts of Phaseout and Voluntary Cancellation

Cyanazine is a broad spectrum herbicide which is registered for the control of many annual grasses and broadleaf weeds in corn, cotton, and sorghum. About 23 - 36 million pounds active ingredient of cyanazine are applied each year in the U.S. Corn accounts for 95 percent of cyanazine usage with between 18 and 21 percent of the field corn acreage treated each year. Cotton accounts for about 3 percent of all usage with between 12 and 20 percent of the cotton acreage treated annually. Sorghum and sweetcorn account for less than 1 percent of all cyanazine usage with between 1 and 3 percent of the sorghum acreage and about 20 percent of sweet corn acreage treated annually.

Cyanazine provides the grower with flexibility of application (preplant,

preemergence, postemergence) and residual activity in addition to burndown in no-till crop management. A second advantage, compared to the widely used atrazine-based products, is that cyanazine is less persistent following application, which results in shorter residual activity. Thus, a significant advantage of cyanazine alone or in mixtures with atrazine, compared to atrazine alone or atrazine in combination with other herbicides, is the ability to plant any triazine-sensitive rotational crop in the fall or the spring following the application without the concern of carryover. This flexibility is extremely important in regions where growing seasons are shorter, which may result in herbicide applications being made later in the spring. A third advantage is that cyanazine offers the grower a wide weed control spectrum, especially against several problem grass species. Therefore, in some cases a second grass herbicide may be unnecessary, or can be used at a reduced application rate.

The Agency has evaluated how the phaseout of cyanazine will impact users as compared to an immediate cancellation. Data and information from publications of the USDA National Agricultural Statistical Service (NASS), USDA/University State Extension Pesticide Use Recommendation Reports, other proprietary marketing research sources, and comments received in response to the triazine PD 1 were used as the basis for this analysis. Although USDA National Agricultural Pesticide Impact Assessment Program (NAPIAP) reports on field corn (1995), cotton (1993), and sorghum (1994) exist, they have limited usefulness to EPA in terms of quantitative estimates of impacts.

The NAPIAP reports generally contain estimates of yield losses and direct costs resulting from the use of some alternative chemicals. The NAPIAP report on corn also includes estimates of crop damage. The yield loss estimates were based on a survey of regional weed scientists. For the corn assessment, scientists from 15 states were interviewed as a group to encourage dialogue. Survey responses were then used as a basis for quantitative estimates of the economic impact of a cancellation of cyanazine and substitution of alternative control methods. The report does not specify the basis for the opinions of the weed scientists. Thus, it is not clear to what extent the opinions of the weed scientists are based on comparative product performance tests or other comparable scientific data. The Agency has concluded that a reliable projection of the comparative performance of pesticide products must

be based on scientifically derived data. Projections based solely on opinions, even the opinions of experts, do not provide a sufficiently reliable basis for the quantitative estimation of economic impacts. Accordingly, the Agency has not relied on the NAPIAP reports to estimate potential economic impacts of the cancellation or phaseout of cyanazine registrations.

The NAPIAP reports are limited in several other respects. The commodity assessments do not focus on cyanazine, nor do they address specific aspects that could affect the impacts associated with its anticipated phaseout. Additional factors that were not considered in the NAPIAP reports include tillage practices, potential for crop injury, farm size, and regional preferences that could also influence the overall economic impacts to users. Perhaps most significantly, the corn and cotton assessments were completed before several newly registered herbicides entered the market, so they were not considered.

The Agency has not adopted the NAPIAP reports' quantitative estimates

of the economic impacts of a cancellation or phaseout, but has used the reports for other purposes in the Agency's analysis. For example, the NAPIAP reports do provide useful information about the manner and extent of cyanazine use. The NAPIAP quantitative estimates have been used only for the limited purpose of illustrating the relative economic differences between the two regulatory options: a complete cancellation or a phase-down of use followed by a complete cancellation. In such an analysis, the accuracy and reliability of the NAPIAP quantitative estimates are not crucial because the Agency is using them for the limited purpose of illustrating the relative relationship between the two regulatory options.

Because the terms and conditions of the cyanazine phaseout call for incremental annual reductions in cyanazine usage beginning in 1997, reaching a maximum of 1 lb/ai/a in 1999, and requirements for closed cab application equipment beginning in 1998 and remaining throughout the phaseout period, the full impacts of the

cyanazine phaseout will not be realized until after 2002, when all use of the chemical is prohibited. However, the Agency does believe that some impacts will occur during the phaseout period as a result of a decrease in the maximum rates allowed per acre and the closed cab requirements.

Most cyanazine users are not expected to be adversely affected by the phaseout until the maximum use rate drops below the rate at which they are currently applying the chemical. For example, the majority of cyanazine usage on corn is applied at rates between 1 and 3 lb/ai/acre. Therefore, the use on corn will not be significantly affected until 1999 when the maximum rate is reduced to 1 lb/ai/acre. Similarly, for cotton, the majority of usage occurs at rates of less than 1 lb/ai/a; therefore, most uses in cotton will remain unaffected, assuming adequate supplies, through 2002, at which time cyanazine will no longer be available for use. Table 5 below presents the frequency distribution of cyanazine acre treatments by application rate for each of the use sites.

Table 5.—Distribution of Cyanazine Usage (Acre Treatments) by Application Rate (1993 - 1994)

Application Rate (lb/ai/acre)	Field Corn	Cotton	Sweet Corn
0 to 1	18%	91%	16%
>1 to 3	72%	8%	81%
>3 to 5	9.8	1%	3%
>5 to 6.5	0.2%	--	--
Total	100%	100%	100%

Source: U.S. EPA; Based on proprietary and publicly available data.

The Agency acknowledges that some benefits are associated with the use of cyanazine throughout the phaseout period; however, quantitative estimates of the impact of the phaseout have not been determined. As discussed earlier, the Agency has used the quantitative estimates of an immediate cancellation as reported by NAPIAP for the limited purpose of illustrating the relative

differences between a phaseout of cyanazine followed by a complete cancellation and an immediate cancellation. The Agency has not relied on the NAPIAP reports to estimate the potential economic impact of the phaseout and cancellation of cyanazine other than to merely illustrate that a phaseout incurs less of an impact to growers than would an immediate

cancellation. The NAPIAP reports estimate that the aggregate economic impacts of an immediate ban of cyanazine would be \$25 million for corn and \$14 million for cotton. In Table 6, the NAPIAP estimates have been used to illustrate the ameliorating effect that the phaseout of cyanazine may have on individual uses (Ref. 12).

Table 6—Allocation of the Impacts of the Phaseout and Voluntary Cancellation of Cyanazine

Year	App Rate (lb/ai/acre)	Field Corn (\$mil)	Cotton (\$mil)	Sweet Corn (\$mil)	Total Impacts (\$mil)
1996	6.5	\$0.00	\$0.00	\$0.00	\$0.00
1997	5	\$0.05	\$0.00	\$0.00	\$0.05
1998	3	\$6.8	\$8.6	\$0.1	\$15.5
1999	1	\$21.4	\$9.0	\$0.7	\$31.1
2000	1	\$21.4	\$9.0	\$0.7	\$31.1
2001	1	\$21.4	\$9.0	\$0.7	\$31.1
2002	1	\$21.4	\$9.0	\$0.7	\$31.1
2003	0	\$25	\$14	\$0.8	\$39.8

While the Agency has used the NAPIAP quantitative estimates of impacts in Table 6 above, the Agency neither accepts nor rejects them. The quantitative estimates are used only to illustrate the relative difference between immediate cancellation and a phaseout.

1. *Field corn.* Between 18 and 21 percent of the 73 million acres planted to field corn receives one or more applications of cyanazine per growing season at an average rate of 1.9 lb/ai/acre. Approximately 22 - 33 million pounds of cyanazine are applied annually. Treatments are predominantly preemergence and preplant incorporated; however, cyanazine combined with atrazine is commonly used in no-till corn as an early post-emergence or burndown agent. Cyanazine is applied alone or in combination with another herbicide approximately 35 and 65 percent of the time, respectively. About 90 percent of cyanazine products are applied broadcast using ground equipment and most of the remaining 10 percent applied as a band treatment. Cyanazine used alone is applied at an average rate of 2.25 lb/ai/acre. When used in combination with another herbicide, cyanazine is applied at an average rate of 1.67 lb/ai/acre.

The majority of users who apply cyanazine to field corn will not be affected until 1999 when the maximum use rate is lowered to 1 lb/ai/a. However, about 10 percent of cyanazine usage does occur at rates of 3 lb/ai/acre or higher on heavier clay soils that generally contain greater than 3 percent organic matter or on soils with greater than 30 percent surface residue. In 1999, when the maximum rate is reduced to 1 lb/ai/a, approximately 82 percent of cyanazine usage will be affected. Compared to an immediate cancellation, the phaseout reduces annual impacts because cyanazine will continue to be available to some growers through 2002. Table 6 above illustrates the ameliorating effect that the phaseout of cyanazine followed by a voluntary cancellation has on corn growers relative to an immediate ban. Efficacious alternatives to cyanazine include atrazine, nicosulfuron, metolachlor, alachlor, dicamba, acetochlor, halosulfuron and prosulfuron.

2. *Cotton.* Cotton is the second largest crop on which cyanazine is used and it accounts for 3 percent of the total cyanazine used in the United States or about 1 - 2 million pounds of active ingredient. About 62 percent of cyanazine usage in cotton are postemergence directed applications, 25 percent are preemergence applications

and 11 percent are layby applications. About 12 - 20 percent of the U.S. cotton acreage received a cyanazine application at an average rate of 0.8 lb/ai/a. Preplant applications were typically made at the rate of 1.5 - 2.0 lb/ai/acre while postemergence applications were made at the rate of 0.5 - 1 lb/ai/a. Alternatives that are available for use on cotton include diuron, fluometuron, oxyfluorfen, prometryn, and the recently registered herbicide pyriithobac-sodium. Since the majority of cyanazine usage in cotton occurs at rates less than 1 lb/ai/a, the phaseout should not adversely impact cotton growers until cyanazine use is prohibited after 2002. Table 6 above illustrates the ameliorating effect that the phaseout of cyanazine followed by a voluntary cancellation has on cotton growers relative to an immediate ban.

3. *Sweet Corn.* Approximately 200,000 to 300,000 pounds active ingredient of cyanazine is applied to sweet corn per year at an average rate of 1.5 lb/ai/acre. About 6 percent of the 164,000 acres of fresh market sweet corn and about 24 percent of the 503,000 acres of processed sweet corn receive cyanazine applications, with Wisconsin, Illinois, New York, Michigan, New Jersey, and Minnesota having significant cyanazine use on this commodity. The heavy usage in Wisconsin is probably due to the restrictions placed on atrazine in that state. There are fewer alternative herbicides registered for use on sweet corn than for field corn, with atrazine being the primary preemergence alternative. Dicamba and 2,4-D are postemergence alternatives for broadleaf weed control and alachlor and metolachlor are alternatives for grass control.

As stated earlier, no published information was available that estimated the impacts of the unavailability of cyanazine for sweet corn production. The Agency calculated estimates for sweet corn based on information that was available for field corn. The economic impact on field corn is adjusted to account for differences between the total acres planted and the per acre value of sweet corn and field corn. The following formula is used to estimate this impact:

$$\text{Sweet Corn Impact} = \text{Field Corn Impact} (\$25 \text{ million}) \times \text{total acres sweet corn} (800,000) / \text{total acres field corn} (70,000,000) \times \text{per acre value sweet corn} (\$850) / \text{per acre value field corn} (\$303).$$

The per acre value of sweet corn is a weighted average of sweet corn grown for the fresh market (224,900 acres, \$373.7 million) and the processed market (516,200 acres, \$256.1 million). The per acre value of field corn was

calculated on the basis of 72.9 million acres with a total crop value of \$22.16 billion. Using the above formula, the annual economic impact of banning cyanazine use on sweet corn is estimated to be \$0.8 million. Annual impacts that result from the phaseout of cyanazine will not significantly impact sweet corn growers until 1999 when the maximum allowable application rate is reduced to 1 lb/ai/a.

Wisconsin sweet corn growers may be severely impacted by the phaseout of cyanazine since it is believed that a large percentage of cyanazine usage in that state is a result of the state restrictions that have been placed on atrazine. In some counties, rate restrictions have reduced the performance of atrazine as a preemergence treatment. Therefore, sweet corn growers may have to resort to using postemergence herbicides to control broadleaf weeds unless new preemergence herbicides are registered. The Agency anticipates that the impact to sweet corn growers will be similar to that anticipated for field corn growers. Table 6 above illustrates the ameliorating effect that the phaseout of cyanazine followed by a voluntary cancellation has on sweet corn growers relative to an immediate ban.

#### *Comments Regarding Benefits of Cyanazine and the Agency's Response*

A number of commenters, including academia and weed extension scientists, grower groups, and chemical producers, submitted comments about the general benefits of cyanazine use in agricultural practices. These general arguments support cyanazine's continued use because of its shorter residual life and therefore less crop rotation restrictions, better control of certain grass weeds other than triazines, effectiveness against germinating and emerged weeds with good burndown action in no-till practices, role in weed resistance management, no drift damage to sensitive crops nearby, and its generally greater flexibility in weed control programs. The Agency acknowledges that there are certain benefits associated with the use of cyanazine and, as required, has considered all of cyanazine's advantages in its assessments.

*Comment:* NCAMP and EWG criticized the methodology of the Agency's analyses of pesticide benefits. NCAMP commented that a comprehensive benefits assessment will demonstrate the appropriateness of cancelling all registrations of the triazines. NCAMP further stated that the Agency's method of assessing benefits is inappropriate because the assessment looks only at

alternative chemical means of controlling weed pests. The EWG commented that the Agency must consider the total social costs of using pesticides in its benefits assessment and that it is not proper to allow a chemical risk to support the production of commodities that are subsidized and where supply exceeds demand. *Agency Response:* Because these comments were not specific to cyanazine, the Agency intends to respond to them later in the Special Review when comments on all triazines are addressed, unless it receives additional comments demonstrating that these criticisms apply specifically to cyanazine.

*Comment:* Griffin provided an assessment of the general benefits of cyanazine that addressed the following aspects of cyanazine: (1) Importance in controlling a wide spectrum of weeds, (2) providing greater crop rotation flexibility, (3) usefulness in no-till practices, (4) weed resistance management, and (5) lower cost than alternative chemicals.

*Agency Response:* The Agency agrees with Griffin that cyanazine offers those benefits as Griffin pointed out; however, the Agency also believes that alternative herbicides are available that provide comparable weed control at similar costs. Earlier in this Notice, the Agency acknowledged many of the same advantages of using cyanazine as Griffin noted.

## VI. Risk/Benefit Analysis and the Agency's Proposed Decision Regarding Special Review

### A. Risks

The terms and conditions of the phaseout and cancellation are expected to reduce risk from use of cyanazine as estimated in the cyanazine PD 1 to zero over the course of the phaseout and depletion of existing stocks. While both users and the public will be subject to some continued risk during this time, the risk to users will decline during the phaseout and depletion of existing stocks due to the imposition of use restrictions and the risk to the public will decline due to the reduction in use rates.

### B. Benefits

In Unit V. of this Notice, a discussion of the impacts of phasing out cyanazine compared to an immediate cancellation is presented. The cyanazine phaseout allows for a gradual reduction in use of the chemical over a period of 7 years.

There are a number of elements inherent in the phaseout of cyanazine that will, in effect, lessen the economic

impact to growers who have used cyanazine in their weed management practices in the past. First, the phaseout should allow growers sufficient time to find suitable alternatives to replace cyanazine, thereby causing little disruption to agricultural production. For example, the majority of cyanazine used is applied to field corn. With the phaseout, there will be little impact to corn growers until 1999 when the maximum allowable use rate drops to 1 lb/ai/a. With all uses, the full impact of the phaseout will not be realized until after 2002 when cyanazine use will be prohibited.

### C. Risks of Alternatives

The Agency has identified the major chemical alternatives to cyanazine in this Notice. Atrazine, one alternative to cyanazine, was placed into Special Review concurrently with cyanazine based on the potential risk of carcinogenicity to humans. No significant risk concerns have been identified with the other alternatives except for 2,4-D, which is currently being considered for possible Special Review pending results of further studies on its carcinogenic potential.

### D. Risk/Benefit Analysis

In light of the terms and conditions of the DuPont and Griffin cyanazine registrations, the Agency has considered the risks and benefits of cyanazine for the remaining 7 years that the pesticide will be allowed for use. During the phaseout, people will be exposed to cyanazine for a limited time period during which application rates will be reduced and closed cab application equipment will be required. As discussed earlier, the Agency believes that the potential risks that may result, while considering the factors of time and exposure imposed by the cyanazine phaseout, will be less than those risks articulated in the PD 1. Further, the Agency has evaluated the impacts of the cyanazine phaseout and has concluded that there are benefits associated with the phaseout of cyanazine.

The phaseout also confers benefits by making it unnecessary to recall and dispose of unused product and by allowing users to reduce costs through various mechanisms such as allowing them time to gradually modify weed management strategies to replace cyanazine. The Agency also considered the costs, time, and uncertainties associated with involuntary imposition of regulatory measures. In the absence of the voluntary cancellation and phaseout, the Agency may have used its authority under FIFRA section 6 to cancel cyanazine registrations. The

Agency believes that this action would have been contested and would have required enormous resources and several years of litigation before a final order could have been implemented. The resources saved by voluntary cancellation and phaseout may now be applied to risk reduction of other products. Also, a contested cancellation would not have brought about the phased-in measures to reduce risk as currently provided for by the terms and conditions of the voluntary cancellation and phaseout. Finally, the outcome of litigation is uncertain in both result and when those results may be achieved; the voluntary cancellation and phaseout has set a firm schedule for the implementation of risk reduction measures and has established a date certain for the final cancellation of cyanazine registrations.

For all of the foregoing reasons, the Agency has determined that implementation of the voluntary cancellation and phaseout of cyanazine will eliminate the potential risks posed by cyanazine identified in the triazine PD 1.

### E. Proposed Decision Regarding Special Review

In view of its determination discussed above, that the terms and conditions of the cyanazine voluntary cancellation and phaseout will eliminate any unreasonable adverse effects posed by the registration of cyanazine, the Special Review need not be continued.

## VII. Request for Voluntary Cancellation

As part of the terms and conditions of all registered cyanazine products, including those of both DuPont and Griffin, voluntary cancellations of all cyanazine registrations will become effective December 31, 1999. Shortly thereafter, the Agency will issue a cancellation order for all cyanazine products. Also, as part of the terms and conditions, EPA is required to provide advance public notification of the voluntary cancellation of cyanazine products as part of the proposal to terminate the Special Review of cyanazine. This section, Unit VII., will serve as the Agency's notification of the requests for voluntary cancellation.

The cyanazine products that, according to the amended terms and conditions of cyanazine registration, will be voluntarily canceled, effective December 31, 1999, are listed below by EPA registration number and product name.

Registration No.	Product Name
352-475	DuPont Cyanazine Technical
352-470	DuPont Bladex (R)4L Herbicide
352-495	DuPont Bladex (R)90 DF Herbicide
352-500	DuPont Extrazine (R)II 4L Herbicide
352-577	DuPont Extrazine (R)II DF Herbicide
1812-364	Griffin Cyanazine Technical
1812-365	Griffin Cynex DF
1812-366	Griffin Cynex 4L Herbicide Liquid
1812-367	Griffin Cynex Extra 4L
1812-368	Griffin Cynex Extra DF

Comments on the requests for voluntary cancellation of these registrations may be submitted to the contact person listed under the FOR FURTHER INFORMATION CONTACT unit of this document during the 30-day comment period provided in this Notice.

Also included in the terms and conditions of cyanazine registrations is a provision for allowing the continued distribution and use of cyanazine end use products beyond the effective voluntary cancellation date. The terms and conditions specifically state that all cyanazine formulated end use products released for shipment by a registrant on or before December 31, 1999, may continue to be distributed and sold in the channels of trade in accordance with labels through September 30, 2002. The terms and conditions further state that use of such existing products in accordance with their labels may continue through December 31, 2002. All labels of cyanazine formulated end use products released for shipment by a registrant after July 25, 1996, will state that the product may not be sold or distributed after September 30, 2002, and that the products may not be used after December 31, 2002. The existing stocks provision will allow any remaining product in the channels of trade to be used, thereby precluding the need for recall and disposal of unused product.

#### VIII. Public Comment Opportunity

During the 30-day comment period, specific comments are requested on the Agency's preliminary determination to terminate the Special Review of cyanazine and on the requests for voluntary cancellation of cyanazine products. The Agency will review and consider any comments received during the official comment period before issuing a final determination on conclusion of the Special Review of cyanazine. All written comments

submitted pursuant to this Notice, except "CBI," will be available for public inspection in Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA Telephone: 703-308-5805.

Comments claimed as CBI must be clearly marked as "confidential," "trade secret," or other appropriate designation on the face of the comments. Comments marked as such will be treated in accordance with the procedures in 40 CFR 2.204(e)(4). Comments not claimed as confidential at the time of submission, or not clearly labeled as containing CBI, will be placed in the public docket. The Agency will consider the failure to clearly identify the claimed confidential status on the face of the comment as a waiver of such claim, and will make such information available to the public without further notice to the submitter.

All comments and information should be submitted in triplicate to the address given in this Notice under ADDRESSES to facilitate the work of EPA and others interested in inspecting them. The comments and information should bear the docket control number, "OPP-30000/60A."

#### IX. Public Docket

A record has been established for the action under docket number "OPP-30000/60A" (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for the document, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in

writing. The official record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

#### X. Terms and Conditions Amending Cyanazine Registrations

On August 2, 1995, EPA accepted DuPont's proposed amendments to its cyanazine registrations that effectively phases out the production of cyanazine for use in the United States by the end of 1999. The amendments also included an incremental reduction of the maximum label rates over the course of the phaseout and a requirement for closed cab application equipment in 1998. The terms and conditions of the amendments apply to all current DuPont cyanazine registrations as well as any new registration that the Agency may approve since the acceptance of DuPont's proposal, including Griffin's recent conditional registrations that were approved by the Agency. As part of the requirements for approval of any future cyanazine registrations, any registrant must agree to comply with all of the same terms and conditions to effectively phaseout cyanazine production for use in the United States by end of 1999. The amended terms and conditions that are required of all cyanazine registrants appear below.

#### Terms and Conditions to Amend Cyanazine Registrations

1. On November 23, 1994, the U.S. Environmental Protection Agency ("EPA") initiated a Special Review under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), for pesticide products that contain a triazine herbicide as an active ingredient, Federal Register Notice, Vol. 59, No. 225 ("the Special Review"). Cyanazine is one of the triazine products subject to the Special Review, and E. I. du Pont de Nemours and Company ("DuPont") is the primary registrant of cyanazine in the United States.

2. EPA's initiation of the Special Review for triazine containing products was based on the Agency's preliminary determination that triazine products trigger risk criteria that indicate these products may present unreasonable risks as described in the Notice of Special Review. This preliminary determination by EPA with respect to cyanazine, however, is not a finding, conclusion or other determination, that cyanazine does in fact present a risk to humans or the environment.

3. The purpose of this letter is to propose a comprehensive listing of the terms and conditions of amendments to DuPont's cyanazine product registrations. The specific mitigation steps proposed in these amendments are designed to reduce the potential for the risk criteria being triggered in the future and to satisfactorily address EPA's concerns over potential risks as described in the Notice of Special Review. DuPont's understanding in agreeing to the



proposed mitigation steps is that if they are required of all current and potential future cyanazine-containing products and registrations, including but not limited to DuPont's cyanazine products and registrations, they will adequately address EPA's concerns that cyanazine products may present risks as described by EPA in the Notice of Special Review. It is DuPont's further understanding that based on this determination, EPA will proceed to conclude the Special Review as to cyanazine as soon as practicable.

4. DuPont's agreement to the proposed amendments set forth herein is not, and shall not be considered as, an admission by DuPont that cyanazine used in accordance with DuPont's registrations and labels triggers risk criteria as described in the Notice of Special Review, or otherwise poses risks to humans or the environment.

5. Cyanazine Risk Mitigation Measures shall be comprised of the following steps: (a) The labels of all cyanazine formulated end use products released for shipment by a registrant<sup>1</sup> after July 25, 1996, for use in the U.S., shall specify seasonal use rates that limit the maximum amount of cyanazine active ingredient that may be applied on a per acre basis as follows:

FOR USE: MAXIMUM SEASONAL USE RATE CAP (AI/ACRE):

Beginning Jan. 1, 1997 5 lbs per acre

Beginning Jan. 1, 1998 3 lbs per acre

Beginning Jan. 1, 1999 1 lb per acre

(b) Subject to all the terms and conditions of these amendments, this letter shall serve as DuPont's request, pursuant to FIFRA, that EPA accept the voluntary cancellation of all of DuPont's existing registrations for formulated end use products containing cyanazine to become effective December 31, 1999. The cancellation date of December 31, 1999, shall become a part of the terms and conditions of DuPont's registrations for formulated end use products that contain cyanazine.

(c) The labels of all cyanazine products released for shipment by a registrant after July 25, 1996, for use in the U.S., shall specify that closed cab application will be required for applications to be made during or after the 1998 use season.

(d) No cyanazine formulated end use products registered for use in the U.S. shall

<sup>1</sup>For the purpose of determining compliance with the proposed terms and conditions of amended registrations as set forth in paragraph 5., whenever the term "released for shipment by a registrant" appears in these amendments, it shall mean the shipment of cyanazine formulated end use products, shipped by or at the direction of a registrant from the facility at which they are finally formulated for distribution, sale and use in the U.S. as evidenced by a bill of lading or other verifiable shipping documents. The term shall not apply to a) shipments of cyanazine formulated end use products by agents, distributors, or dealers who receive and further distribute cyanazine products to customers, or b) to cyanazine technical products shipped within the U.S. for formulation into end use products, or c) to shipments of cyanazine technical or formulated end use products for export. Any formulated end use product containing cyanazine technical products and registered for use in the U.S. shall be subject to the terms and conditions of paragraph 5 of this letter.

be released for shipment by a registrant after December 31, 1999.

(e) EPA shall authorize existing stocks of all cyanazine formulated end use products that have been released for shipment by a registrant of such products on or before December 31, 1999, to continue to be distributed and sold in the channels of trade in accordance with their labels through September 30, 2002. EPA shall authorize the continued use of such existing stocks in accordance with their labels through December 31, 2002. Labels of all cyanazine formulated end use products released for shipment by a registrant after July 25, 1996, shall bear the following statements: "This product may not be sold or distributed after September 30, 2002" "This product may not be used after December 31, 2002."

(f) The public will have advance notification of the voluntary cancellation of DuPont's cyanazine formulated end use registrations and the existing stocks provisions provided for herein as part of the conclusion of the Special Review, and DuPont shall have no obligation to recover or recall any cyanazine products, or to reimburse, or otherwise compensate or provide additional notice to any purchaser or other party in connection with or as a result of the voluntary cancellation provided for herein.

(g) cyanazine technical products released for shipment by a registrant after July 25, 1996, shall bear labels stating that any formulated end use products that are made from the technical products and that are registered for use in the U.S., shall be subject to the terms and conditions of cyanazine registrations set forth in paragraph 5 of this letter.

6. (a) It is DuPont's understanding that upon its submission to EPA of a signed copy of this letter proposing amendments to its registrations, EPA will commence such steps as are necessary to approve finally the amendments and to conclude the Special Review of cyanazine, without requiring further mitigation steps by DuPont, and that EPA will complete such final Agency action, including any public comment or required notice to other federal agencies, as soon as practicable. In the event EPA is unable to so approve the amendments or to finally conclude the Special Review, for whatever reason, or if after August 2, 1995, and prior to the date EPA finally approves these amendments and finally concludes the Special Review, another party obtains a cyanazine registration that does not contain the terms and conditions set forth in these amendments, for whatever reason, these amendments may, at DuPont's election, be withdrawn and be without effect, and the current terms and conditions of DuPont's cyanazine registrations shall remain in effect. In such event, DuPont will retain all of its rights to participate fully in the Special Review, or any Agency or judicial review of the same, or to contest any regulatory action that may be initiated against its products and registrations, pursuant to FIFRA or other applicable laws and regulations, as it deems appropriate.

(b) In the event another party obtains a registration of a cyanazine product that does

not require the terms and conditions of registration as specified in this letter, including cancellation as of December 31, 1999, or said terms and conditions are proposed or imposed upon another party's registrations, but are stayed or enjoined in whole or in part by the Agency or any court, EPA agrees to permit DuPont to continue its registrations in effect beyond December 31, 1999, and/or amend its cyanazine registrations, on a specific use and/or site specific or use rate basis, in order to delete any term or condition of registration set forth in this letter that is not required of the other party or as a term or condition of that party's registration, and to make such other amendments to its cyanazine registrations, including but not limited to adding new uses or application methods, as are necessary so that DuPont's cyanazine registrations may contain the same terms and conditions as are contained in the other party's registrations. Any such amendments are to be accomplished in accordance with the requirements of FIFRA.

7. On April 16, 1992, EPA issued a Data Call In for cyanazine (the "DCI"). DuPont has completed and submitted all of the studies requested in the DCI. EPA agrees that DuPont has submitted all of the studies requested by the DCI, and that EPA will not request further data from DuPont in connection with said DCI. Nothing contained in these amendments shall be interpreted as restricting EPA's authority to issue a future Data Call In, or otherwise to regulate cyanazine registrations pursuant to FIFRA, should the Agency determine that there is significant new evidence about potential unreasonable risks to the environment presented by use of products containing cyanazine. DuPont shall retain all of its rights under FIFRA and other applicable laws and regulations to challenge any such action by EPA.

8. Upon EPA's final acceptance of these amendments, and the Agency's final action concluding the Special Review in accordance with the amendments and understandings set forth herein, DuPont agrees to waive its rights to challenge EPA's final action on the Special Review, or the terms and conditions of label amendments that are required by these amendments, in any court or administrative forum, and agrees not to assist or encourage any other party to challenge EPA's final actions. Except as expressly set forth in these amendments, DuPont shall retain all of its rights under FIFRA, and other applicable laws and regulations, to challenge any action, proceeding or determination by EPA, or to challenge or intervene in any action by or involving a third party, with respect to the registration of DuPont's or any other party's cyanazine products.

## XI. References

1. U.S. Environmental Protection Agency. Notice of Receipt of Requests to Voluntarily Cancel Certain Registrations. Federal Register Notice (60 FR 56333). November 8, 1995.

2. U.S. Environmental Protection Agency. Atrazine, Simazine, and Cyanazine; Notice of Initiation of Special Review. Federal Register Notice (59 FR 60412). November 23, 1994.

3. U.S. Environmental Protection Agency. Letter from Lynn R. Goldman to Jane D. Brooks, Dupont Agricultural Products. August 2, 1995.

4. U.S. Environmental Protection Agency. Notice of Pesticide Registration. November 6, 1995.

5. U.S. Environmental Protection Agency. Notice of Pesticide Registration. September 18, 1995.

6. U.S. Environmental Protection Agency. Notice of Pesticide Registration. February 8, 1996.

7. U.S. Environmental Protection Agency. Notice of Pesticide Registration. February 9, 1996.

8. U.S. Environmental Protection Agency. Notice of Pesticide Registration. February 12, 1996.

9. U.S. Environmental Protection Agency. Memorandum from Denise Keehner, Office of Pesticide Programs, Environmental Fate and Effects Division. Transmittal of EFED Review of Comments Including DuPont's on the PD 1 Related to Ground Water and Surface Water for Cyanazine. November 3, 1995.

10. DuPont Agricultural Products. Letter from Tony E. Catka. "Cyanazine Mixer/Loader/Applicator Occupational Cancer Risk Estimates." October 19, 1994.

11. U.S. Environmental Protection Agency. Memorandum from Olga Odiott, Office of Pesticide Programs, Health Effects Division. "DuPont's Cyanazine Occupational Exposure Estimates." October 26, 1995.

12. U.S. Environmental Protection Agency. Biological and Economic Assessment of the Cyanazine Phaseout. February 9, 1996.

Dated: February 26, 1996.

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