

peroxide bond is weak, transformation to acetic acid, water and oxygen is very highly favored thermodynamically (1993 RED). The degradation products of peroxyacetic acid are acetic acid (which is generally regarded as safe in food up 0.15%, see 21 CFR 184.1005), water and oxygen. Therefore, exposure of the pesticide chemical (from the use proposed in this petition) to the U.S. general population should not occur.

G. Effects on the Immune and Endocrine Systems

Peroxyacetic acid is not structurally similar to any known chemical capable of producing adverse effect on the endocrine system.

H. International Tolerances

The petitioner understands that there are no current established Maximum Residue Levels (MRL) for peroxyacetic acid.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-6228-7]

Response to Recommendations from the Children's Health Protection Advisory Committee Regarding Evaluation of Existing Environmental Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA asked the federal Children's Health Protection Advisory Committee (CHPAC) to recommend five existing standards that may merit reevaluation in order to further protect children's environmental health. This document includes EPA's response to the CHPAC recommendations. EPA will reevaluate the chloralkali National Emission Standard for Hazardous Air Pollutants (mercury); the implementation and enforcement of the (Farm) Worker Protection Standards; pesticide tolerances for organophosphates (chlorpyrifos, dimethoate, methyl parathion); atrazine pesticide tolerances and Maximum Contaminant Level in drinking water; and will review indoor and ambient air quality as they relate to asthma. EPA's decision to reevaluate is based in large part on recommendations from the Children's Health Protection Advisory Committee and public comments in response to a **Federal Register** document of October 3, 1997.

In September 1996, EPA issued a report on Environmental Health Threats to Children (EPA 175-F-96-001) that described how and why children are affected by an array of complex environmental threats to their health. The report included a National Agenda to Protect Children's Health from Environmental Threats in which EPA called for a national commitment to ensure a healthy future for our children. We called on national, state and local policy makers—as well as each community and family—to learn about the environmental threats our children face; to participate in an informed national policy debate on how together we can best reduce health risks for children; and to take action to protect our Nation's future by protecting our children.

The first element of the National Agenda committed the Administration to “. . . ensure, as a matter of national policy, that all standards EPA sets are protective enough to address the potentially heightened risks faced by children—so as to prevent environmental health threats wherever possible—and that the most significant current standards be reevaluated as we learn more.” We further state that “. . . EPA will select—with public input and scientific peer review—five of its most significant public health and environmental standards to reissue on an expedited basis under this new policy.”

Background

In order to meet our commitment to public input, EPA sought advice through two channels: formal notice and comment, and the formation of a Federal Advisory Committee composed of individuals representing diverse viewpoints. On October 3, 1997, EPA issued a document and request for comments from the public as to existing EPA standards that, if revised as a result of review and evaluation, would strengthen and increase children's environmental health protection. EPA received comments from 18 individuals and organizations. (Attachment A to this document includes the list of submitters, a summary of the comments, and EPA's response to the public comments.) Further, on September 9, 1997, EPA issued a document in the **Federal Register** that it had established a Children's Health Protection Advisory Committee (CHPAC) under the Federal Advisory Committee Act, Public Law 92-463, to advise the Administrator on various issues of children's environmental health protection.

One of the first actions undertaken by the CHPAC, at the request of EPA, was

to develop a set of recommendations to the Administrator concerning which existing rules EPA should reevaluate. They started by reviewing the public comments that were submitted in response to the October 3, 1997, **Federal Register** document. Based on extensive deliberations the CHPAC submitted their recommendations in a consensus report dated May 28, 1998. (See Attachment B for the selection criteria used by the CHPAC in their deliberations.) The following section lists the CHPAC recommendations, excerpts the discussion that accompanied the recommendations in the report (in italics), and outlines EPA's response.

We congratulate the Children's Health Protection Advisory Committee for their success in deliberating and recommending actions to improve EPA's regulations. We believe that EPA's response to these recommendations advances our goal to better protect our Nation's children.

FOR FURTHER INFORMATION CONTACT: If you have a need for further information you may write to Meg Kelly, Office of Children's Health Protection, USEPA (MS1107), 401 M Street, SW, Washington, D.C. 20460; (kelly.margaret@epa.gov).

SUPPLEMENTARY INFORMATION:

CHPAC Recommendation: Reevaluate the National Emission Standard for Hazardous Air Pollutants (NESHAP) for Chloralkali Plants

CHPAC Report Discussion: “The CHPAC recommends that EPA take a holistic approach to evaluate all sources of mercury emissions. Mercury is a relevant issue to more than one media (air, water), which contributes to its entry into the environment, for example, by electricity (coal-burning) generation, incineration and discharge into water sources. Human exposure occurs primarily through fish consumption. Mercury exposure is associated with adverse health effects in humans. Depending on dose, the effects can range from severe to less severe, most notably, neurological, developmental, and reproductive effects.

By the end of 1998, EPA is scheduled to complete a multimedia strategy addressing mercury. We support EPA's multimedia approach and schedule for the issuance of this strategy.

We encourage EPA to proceed diligently with implementation to protect children from mercury emissions, including those from municipal, medical, and hazardous waste combustion.

Although the CHPAC selected the National Emission Standard for

Hazardous Air Pollutants (NESHAP) for chloralkali plants for reevaluation, EPA resources should not be diverted from the evaluation of other larger sources of mercury emission. Important criteria for its selection are that the standard has not been re-evaluated or revised since its promulgation in 1973, children's health was not considered in the original development of the standard, and new information and data based on peer reviewed science suggest that risks to children and the persistent and bioaccumulative nature of mercury were not considered during the setting of the standard.

The CHPAC recognizes the Water Quality Criteria Standard as one means by which the EPA can regulate the prevention of contaminated fish by mercury and ensure children's protection from hazardous levels of mercury. The CHPAC recommends that EPA address the largest sources of mercury emissions expeditiously and prevent further contamination of fish by revising the Water Quality Criteria Standard. Studies have shown that once mercury enters water, either directly or through air deposition, it can bioaccumulate in fish and animal tissue at the top of the food chain in concentrations much greater than those found in water.

Another specific concern is the emission of mercury from electric (coal-burning) utility boilers (regulatory determination by the EPA is due in November 1998). Important criteria for its selection are that there is currently no regulation of hazardous air pollutant emissions, such as mercury, from electric utility boilers, and electric utility boilers are the largest contributor of overall anthropogenic sources of mercury emissions in the United States (EPA Mercury Report to Congress 1997)."

EPA's Response: EPA agrees with the CHPAC recommendation that the NESHAP for chloralkali plants be revisited and has begun a process to revise this standard. A proposed rule will include emissions limits based on control technology and on management practices. EPA projects a proposal date of November 1999, and expects to issue a final standard in November 2000. In order to ensure protection of children, the Office of Air and Radiation (OAR) will analyze the risk from chloralkali plants to support the rule making—an unusual step for a technology-based standard. However, OAR believes the risk assessment will provide us with information on potential children's risks that is important to determining the appropriate level of the standard. Results of the risk analysis may be used

to justify setting a standard more stringent than the maximum achievable control technology (MACT) floor, but any standard set will be no less stringent than the floor.

Discussion: On November 16, 1998, EPA issued a draft Multimedia Strategy for Priority Persistent, Bioaccumulative, and Toxic Pollutants (<http://www.EPA.gov/pbt/strategy.htm>). This strategy includes a multifaceted draft Action Plan for Mercury. EPA believes that this action plan addresses the concerns expressed by the CHPAC in their report. It recognizes the multimedia threat posed by methyl mercury—the compound to which mercury is transformed through natural environmental processes—and the need to control human exposure to methyl mercury, through multiple concerted approaches targeted at air, water, sediment and land. Further, EPA is proposing additional reporting of mercury releases under the Toxic Release Inventory to improve citizens' right to know about releases in their environment.

EPA has taken several important steps to reduce the levels of mercury, including reducing emissions from municipal waste combustors and medical waste incinerators. These combined actions, once fully implemented (December 2000 for municipal waste combustors; September 2002 for medical waste incinerators) will reduce mercury emissions caused by human activities by 50% from 1990 levels. EPA also entered into a partnership with the American Hospital Association whose goal is to virtually eliminate hospital mercury waste by the year 2005.

Further, final regulations for hazardous waste combustion facilities (incinerators, cement kilns, lightweight aggregate kilns) are expected to be promulgated in February 1999. The EPA is responding to extensive public comment including new emissions data and comments on the methodology used to estimate mercury emissions from these facilities. The final rule is expected to achieve a substantial overall reduction in mercury emissions from these hazardous waste combustion facilities.

The CHPAC highlighted their concern that EPA resources not be diverted from the evaluation of other larger sources of mercury emission. EPA assures the CHPAC that the Mercury Action Plan addresses all known important sources of mercury. For example, EPA is also developing regulations to limit emissions of hazardous air pollutants, including mercury, from five additional source categories—industrial,

commercial, other nonhazardous solid waste combustors, gas turbines, and stationary internal combustion engines. Proposed regulations are due by the end of the year 2000. In addition, EPA will consider the impacts to children's health along with many other factors (e.g., controllability and costs) as part of the regulatory determination for coal-fired electric utility power plants.

EPA agrees with the CHPAC that we should revise water quality criteria that are used by states and tribes to establish enforceable water quality standards. EPA's Office of Water (OW) is accelerating development of a revised water quality human health criterion for mercury which will reflect two major departures from past approaches:

- A revised human health methodology will provide for use of bioaccumulation factors to estimate the build up of mercury in fish-tissue rather than using bioconcentration factors. This means that water quality criteria will now be based on biomagnification in the food chain. An improved means to estimate fish consumption is also included. A draft revised Water Quality Criteria Methodology for Human Health was published in August 1998. Although not regulations, these criteria do propose fish intake and body weights that more accurately reflect actual characteristics of women of childbearing age and children. OW is taking public comment on the proposal. A final human health criteria methodology is projected to be available by the end of 1999.

- An updated human health risk assessment will result from an interagency review of recent human data on methyl mercury. This review will concentrate on levels of exposure to mercury associated with subtle neurological endpoints and is aimed at achieving consensus among Federal agencies on estimates of human risk. A workshop was conducted in November 1998. In addition, Congress required, in the report that accompanied EPA's 1999 appropriation, a 18-month National Academy of Sciences study and recommendation on the reference dose for methyl mercury. This study will begin in January 1999. A peer review of application of the new methodology to methyl mercury is projected for completion by mid 2000.

Finally, the CHPAC report indicated concerns about emissions of mercury from electric (coal-burning) utility boilers. In order to support a regulatory determination (now required by December 15, 2000) and potential future regulatory action, EPA will gather high quality emissions data about coal-fired electric generating plants to address

current uncertainties about mercury emissions. To accomplish this, we are requiring all coal-fired power plants above 25 megawatts (MW) to provide the results of analysis to determine the mercury content of the coal they are burning. In addition, a sample of plants will be required to perform stack testing for quantity and species of mercury emissions. The information obtained from this effort will allow EPA to calculate the amount and species of mercury emitted by each coal-fired plant above 25 MW. This information will be available to the public.

CHPAC Recommendation: Reevaluate the (Farm) Worker Protection Standards

CHPAC Report Discussion: "Children may be exposed to pesticides through employment in farm work, by eating fruits and vegetables directly from the fields while at work, or by drift from field applications to neighboring residential areas and schools. Pregnant and lactating women who work in farm fields or reside in neighboring areas can also expose fetuses and neonates to pesticides. The current (farm) worker protection standard has not considered these pesticide exposures to children. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA has the authority to regulate these childhood and prenatal exposures to pesticides through the worker protection standard including labeling, reentry intervals, personal protective equipment, worker education and training, and posting and signs.

The CHPAC recommends that EPA expeditiously re-evaluate the worker protection standard in order to determine whether it adequately protects children's health. In its reevaluation, EPA should, for example, consider using standardized data on size and age-specific weight and height for modeling children's exposure when more specific data on children's exposure to individual pesticides may be lacking."

EPA's Response: EPA agrees with CHPAC that improvements are needed in its regulatory efforts to protect the health of children in agricultural areas. Because the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) gives EPA broader authority than identified by CHPAC, however, EPA intends to carry out a more comprehensive set of initiatives than recommended by CHPAC. Specifically, EPA is working, or planning work, in the following areas: consistency and effectiveness in state implementation and enforcement of the Worker Protection Standards (WPS); application

of available regulatory tools; verification of national compliance; determination whether the regulation is meeting its goal; education of farmers, workers, and state regulators; reassessment of the scope, quality, and medium of safety training; and educating the medical community. In particular, we agree that we need to better address the safety needs of women and children as agricultural workers. The following discussion outlines steps that EPA is prepared to take to improve the health of farm worker children in response to the specific CHPAC recommendations.

EPA is committed to conduct an internal review of the process used to establish entry intervals for pesticides in order to affirm that the process adequately factors in the special needs of children and women employed as farm workers. The review will be conducted in 1999. However, it is not EPA's plan to repropose the Worker Protection Standard (WPS) because we believe implementation and enforcement of the standard can be improved to protect the health of children who work in agriculture without a regulatory change.

EPA's Office of Pesticide Programs is in the process of revising its exposure assessment Standard Operating Procedures. We anticipate the result will be to account for and better characterize pesticide exposure scenarios involving spray drift and other residential exposures that may occur from pesticide use in nearby agricultural areas or from agricultural workers who may carry pesticide residues into the home.

On a broader level, EPA is proposing a national assessment of implementation and enforcement of the WPS. The assessment will include the establishment of a worker protection assessment group composed of EPA, the U.S. Department of Agriculture (USDA), the Department of Labor (DOL), the Department of Health and Human Services (DHHS), state regulators, state extension service safety educators, farm worker advocacy groups, farm worker service/training associations, agricultural employer associations, farm worker clinicians' networks, and others to provide national direction to state programs. The goals of the group will be to:

- Assess the current program status;
- Generate a consortium of interests that can effect change in the programs;
- Provide a means to foster the partnerships essential to make the program work;
- And most important, to provide a continuing forum to focus and resolve worker protection issues.

The worker protection assessment group will be established and begin work in 1999. It will develop a strategic plan for the national worker protection program and issue annual reports detailing accomplishments and progress toward achieving its goals.

Discussion: EPA will also collect actual data on pesticide exposures by co-funding and providing consultation to the National Institute for Occupational Safety and Health (NIOSH) for pesticide case reporting projects (surveillance systems) in five states: California, New York, Texas, Oregon and Florida. The surveillance systems, located in the state health department, include the collection of reports on human incidents of pesticide intoxication, review of trends in disease over time and the response to outbreaks of disease. There is emphasis placed on outreach and training to involved groups within the community (industry/farmers, workers, community residents, health care providers and local government). Whenever possible, information is obtained on take-home exposures to children as well as evaluation of child or adolescent farm work. It is anticipated that preliminary data on the first year of pesticide case reports for these five states will be available in late 1999.

In April 1998, EPA held a workshop to initiate a multi agency effort to create a national plan for increasing training and awareness among health care providers of pesticide-related health conditions ("Pesticides and National Strategies for Health Care Providers"). This initiative is led by EPA in partnership with the DOL, HHS and USDA. Workshop proceedings have been distributed and working groups are developing implementation strategies. A national meeting is anticipated in late 1999 to provide a forum for public discussion of the final recommendations.

EPA will also continue its role in providing coordination and expertise to the following important activities targeted at children who work in agriculture:

- EPA initiated a study of pesticide exposure among children living along the US-Mexico border as part of the Border XXI environmental health project. Currently, the study design is being developed. EPA staff will provide medical consultation to the research team.

- In 1998, the first federally-funded research centers dedicated solely to studying children's environmental health hazards were selected. The joint EPA/HHS funding created eight "Centers of Excellence in Children's

Environmental Health Research." Two of these centers involve farm worker children: The University of California at Berkeley will evaluate pesticide exposures and related growth / developmental status in the Salinas area, and the University of Washington will study the health of children living in the farm worker community in Yakima Valley.

- EPA contributed funds and had representation on the planning committee for the Pediatric Environmental Health Conference to be held in San Francisco in September 1999. The conference will focus on pediatric environmental health and will target health care providers as well as the trainers/professors of health care providers. Sections of the conference will deal with pesticides and children's health.

CHPAC Recommendation: Reevaluate the Atrazine Drinking Water Maximum Contaminant Level (MCL) and the Atrazine Pesticide Tolerance

Contaminant Level (MCL) and the Atrazine Pesticide Tolerance

CHPAC Report Discussion: "Atrazine is a herbicide that belongs to the triazine class. Atrazine has been linked to adverse health effects including cancer and birth defects. Atrazine has been detected in drinking water throughout the Midwest and other parts of the nation. When EPA established the tolerance and 1991 drinking water standards for atrazine, children's differential exposure was not considered and children's differential susceptibility was not fully evaluated. New information has since become available to the EPA concerning the mechanism of action underlying its carcinogenic effect. Hormonal effects were further investigated and triggered the need for the reevaluation of both the carcinogenic effects of this compound as well as the developmental and reproduction studies. Reviewing the tolerances and the established drinking water standard in concert will provide EPA with an opportunity to evaluate a chemical's impact on children's health via aggregate routes of exposure. Reconsideration of the tolerances and drinking water standard for atrazine should be given top priority in EPA's implementation of the Safe Drinking Water Act and the Food Quality Protection Act."

EPA's Response: The preliminary risk assessment for atrazine will be prepared by December 1999 and published as part of a Reregistration Eligibility Document by June 2000. The public will have 60 days to comment on the Atrazine

findings following publication of this document.

The drinking water standard will be based on the new risk assessment conducted by the pesticide office. Reevaluation of the atrazine Maximum Contaminant Level (MCL) should be complete approximately 18 months after the risk assessment is completed.

Discussion: The triazine pesticides are in the first tier of pesticides that EPA is re-evaluating in order to comply with the requirements of the Food Quality Protection Act. Scientific questions regarding the health effects of the triazine pesticides should be resolved by September 2000. EPA's Science Advisory Board (SAB) and Science Advisory Panel (SAP) will be examining key issues related to the risk assessment, including cancer mechanism, in the fall of 1999. Once EPA receives comment from the SAB/SAP, the Agency will complete a comprehensive review of the risks and benefits of the use of atrazine, including the following assessments:

- Evaluate the concentrations of the pesticide in water and assess risk in drinking water for infants, children, and adults;
- Assess dietary risk from ingestion in adult and children's diet;
- Determine requirements for use of personal protective equipment, re-entry time, and application method, including an evaluation of children workers and re-entry intervals;
- Assess ecological risk; and
- Consider economic factors and alternative pesticides during the analysis of benefits.

CHPAC Recommendation: Reevaluate Pesticide Tolerances for Methyl Parathion, Dimethoate, and Chlorpyrifos

CHPAC Report Discussion: "EPA scientific panels have found that organophosphate and carbamate insecticides disrupt the central nervous system via a cholinesterase inhibition mechanism of toxicity. Because children's central nervous systems continue to develop until puberty, they are particularly vulnerable to the effects of some neurotoxins. Children can be exposed to these insecticides through food, homes, schools, employment, and other sources.

Data indicate that children's patterns of dietary intake are distinct from adults' patterns. When EPA established the tolerances for these insecticides, children's differential exposure was not considered and children's differential susceptibility was not fully evaluated. Of the 39 pesticides registered for use on food, thirteen are detected in food according to FDA and USDA pesticide

residue data. Five of these account for 90 percent of the dietary risk of neurotoxicity and three (methyl parathion, dimethoate, and chlorpyrifos) represent the bulk of that risk. Reconsideration of the tolerances for these three pesticides should be given top priority in terms of data collection and other necessary steps in EPA's implementation of the Food Quality Protection Act."

EPA's Response: The preliminary risk assessment for dimethoate was released for a 60-day public comment period on September 9, 1998. The next steps in the process for this pesticide include analyzing the comments received; deciding whether to revise the risk assessment based on the comments; and proposing risk mitigation measures to address any concerns, including dietary, worker, and ecological, identified in the risk assessment. By the end of January 1999, EPA will issue a revised risk assessment and any proposed risk mitigation measures for 60 days of public comment.

The preliminary risk assessment for methyl parathion has been completed, reviewed by the registrant for errors, and is now available for public comment. The public will have 60 days to comment on the risk assessment. Following public review, the assessment for methyl parathion will follow the same process as dimethoate.

The preliminary draft risk assessment for chlorpyrifos is being worked on and is expected to be completed in Spring 1999. Following completion, it will proceed in the same way as dimethoate and methyl parathion.

Discussion: Organophosphates are in the first tier of pesticides that EPA is re-evaluating in order to comply with the requirements of the Food Quality Protection Act. EPA is presently working on a methodology to assess cumulative risks posed by the organophosphate pesticides as a group, and will explicitly include data on children's risk in the risk assessments. We expect to propose such a methodology in the summer of 1999 for a 60-day public comment period. Moreover, EPA is following a process recommended by the federal Tolerance Reassessment Advisory Committee to increase the transparency of EPA's risk assessments and decisions, and allow the public to participate in the process.

CHPAC Recommendation: Review the following areas as they relate to Asthma:

- Indoor Air Quality
- Ambient Air Quality Standards (Particulate Matter, Sulfur Dioxide)

CHPAC Report Discussion: "The CHPAC recognizes the high priority in addressing childhood asthma and the need to better understand and respond to the relationship of asthma prevalence and exacerbation to indoor and ambient air quality. It also recognizes that indoor air quality, which can significantly aggravate and may contribute to the development of childhood asthma, demands timely scientific study and action. Definitive progress in these areas using a sound scientific approach will result in a significantly improved health outcome for all children. EPA's Science Advisory Board and the Presidential/Congressional Commission on Risk Assessment and Risk Management have also identified indoor air pollution as a high human health risk warranting additional attention.

Selecting a broad area rather than a single standard was a purposeful decision by the CHPAC designed to encourage a comprehensive examination of all aspects of air quality. The CHPAC strongly desired to address asthma. The CHPAC encourages a holistic review of outdoor and indoor air quality and strongly feels that this is a more useful recommendation than the identification of a specific standard. Examples include evaluating the effectiveness of existing EPA guidance on indoor air quality relating to asthma and additional emphasis on protecting the health of children with asthma in development of PM monitoring and research programs.

By including this broad category, the CHPAC is hopeful that EPA will take a leadership role by providing impetus for action with regard to indoor air (including environmental tobacco smoke (ETS), pesticides, biological contaminants, and volatile organic chemicals) through a coordinated strategy with other federal agencies. The CHPAC recommends that EPA continue to support sound research programs on concentrations and exposure assessments of ambient air pollutants on asthma, such as PM, and to obtain timely exposure data for risk assessments in areas such as the short-term SO₂ standard.

The CHPAC recognizes that much of the value of the regulatory re-evaluation effort is identification of process improvements that can be applied to future risk assessment and rulemaking efforts. The CHPAC further recognizes that a disciplined approach in the area of air quality can have high learning value, given the breadth and diversity of the issues and the potential to promote multi-agency coordination and cooperation."

EPA's Response: EPA strongly agrees with the CHPAC's recommendation that EPA undertake a fully integrated effort to address both indoor and outdoor pollution factors that contribute to childhood asthma. As CHPAC is aware, asthma rates in the U.S. have been increasing at an alarming rate and particularly troubling is the fact that asthma has increased 160% in children less than five years of age since 1980. Approximately 5.5 million children now suffer from asthma; 150,000 are hospitalized each year; and asthma is the leading cause of school absenteeism due to chronic illness.

Efforts to integrate and expand the Agency's commitment to addressing the multifaceted asthma issue are being addressed under the President's Task Force on Children's Environmental Health Risks and Safety Risks. The Task Force has identified asthma as one of four Priority Areas to receive special emphasis. EPA, along with the Department of Health and Human Services and other Federal Agencies, is developing a comprehensive cross-government action plan to address asthma. The action plan will identify the research and surveillance activities needed to understand the causes of childhood asthma and the scope of the problem as well as identify the public health practice and outreach needs and opportunities to begin to turn the tide on childhood asthma rates. Experts on asthma-related and environmental issues from EPA, the Department of Health and Human Services, and the Department of Housing and Urban Development are collaborating in this effort.

The action plan calls for substantially increased emphasis on asthma research, asthma surveillance activities, and increased implementation of public health programs to reduce childhood asthma by reducing environmental asthma triggers. The action plan places significant emphasis on reducing the disproportionate burden of asthma on minorities and children living in poverty, on community-based programs, effective partnerships, and evaluation of programs. The action plan will contain specific recommendations and key actions to be taken in the following areas:

- Strengthening and accelerating research on environmental factors that cause or worsen asthma;
- Expanding implementation of public health programs that use the best available scientific knowledge to reduce environmental exposures to asthma triggers, including indoor and ambient air pollution;

- Establishing a nationwide surveillance system for collecting and analyzing asthma data; and,
- Identifying and eliminating inequalities in the health burden of asthma with respect to poor and minority children.

In FY99, EPA is substantially expanding its programs to address the environmental factors that affect asthma in children:

- EPA has funded eight Centers for Children's Environmental Health and Prevention Research, five of which are specifically focused on asthma.

• EPA is also developing an integrated research strategy to address ambient air pollution sources such as ozone and particulate matter that may exacerbate asthma, as well as to better understand the relationship between asthma and indoor pollutants such as dust mite and cockroach allergen, molds, and other indoor contaminants such as pesticides and VOC's.

- We are also funding a comprehensive assessment of the role of indoor allergens in the induction and exacerbation of asthma through the National Academy of Sciences Institute of Medicine.

• EPA is expanding education of physicians and other health care providers, teachers, school administrators, children and parents about those factors that are known to contribute to childhood asthma triggers such as tobacco smoke and allergens in homes, schools and day care facilities. We will place significant emphasis on evaluating existing and developing programs for effectiveness.

Attachment A—Public Comments Responding to Federal Register Document Dated October 3, 1997 (62 FR 51854-51855), "Review and Evaluation of EPA Standards Regarding Children's Health Protection From Environmental Risks"

In the October 3, 1997, **Federal Register** document EPA asked the public to submit comments to help the Agency determine which five existing standards merited reevaluation for the following reasons:

- New scientific information or data are available indicating adverse effects on children;
- There is a new understanding of routes of exposure to children;
- The regulated substance is persistent and bioaccumulative;
- New methodologies to evaluate human health risks are available;
- New epidemiology studies exist;
- New toxicity studies exist;
- New environmental monitoring studies exist.

Following is a list of the 18 organizations or individuals who commented on the document:

American Lung Association
American Water Works Association
(AWWA) Government Affairs Office
California Communities Against Toxics
Chemical Manufacturers Association
(CMA)
Chemical Specialties Manufacturers
Association
Children's Environmental Health
Network
Citizen-at-Large
City of Milwaukee Health Department
The Connecticut Agricultural
Experiment Station
ESC Consulting
Florida International University
Missouri Department of Health
National Association of County and City
Health Officials (NACCHO)
The National Center for Lead-Safe
Housing (The Center)
Natural Resources Defense Council
Rhone-Poulenc
Seeger, Potter, Richardson, Luxton,
Joselow & Brooks, L.L.P for the Lead
Industries Association, Inc. (LIA)

State of Wisconsin

Following is a summary of comments submitted by the 18 organizations or individuals in response to the **Federal Register** document:

1. EPA should also include recently promulgated standards as part of the standard review.

2. EPA should select for review the national air quality standards for particulate matter, nitrogen dioxide and sulfur dioxide

3. The American Lung Association (ALA) filed a legal challenge to EPA's decision not to revise the national air quality standard for sulfur dioxide. Regardless of the court decision, ALA recommends that EPA include the sulfur dioxide standard for review and evaluation.

4. AWWA does not believe that at this time there is sufficient data to warrant a change in existing drinking water regulations.

5. The Safe Drinking Water Act (SDWA) typically considers children separately in risk assessment process.

6. The Safe Drinking Water Act (SDWA) requires EPA to review existing drinking water standards every six years which will ensure new data and information will be considered.

7. Concerned about the impact to children's health from persistent, bioaccumulative toxins (PBTs)—dioxins, PCBs and mercury.

8. PCBs are toxic to children during brain development.

9. Millions of lbs. of PCBs remain in use and dispersed into the environment through mismanagement and accidents.

10. The latest mercury study and ATSDR Toxicological Report on mercury cannot correctly quantify or locate mercury emissions due to inadequate monitoring and reporting.

11. EPA reports that 1.6 million women/children are at risk from mercury poisoning.

12. Perchlorate is an endocrine disrupting chemical that affects children's brain development; action level should be set to protect children not adults.

13. Despite the FQPA, we remain concerned about the exposure of children to pesticides through food and non-food exposures. There is evidence of increased rates of leukemia in homes with pesticide application.

14. A programmatic review of PBTs and their impact on children is absolutely necessary.

15. Many of the hazardous air pollutants, for which no emission limits are being set, are reproductive and developmental toxicants.

16. Standard as defined in the **Federal Register** document is too narrow.

17. EPA should:

(a) more closely coordinate efforts to protect children's health with other federal agencies to ensure that limited federal resources are focused on the biggest health risks to children;

(b) consider for review certain regulatory standards that due to their imposition, inadvertently increase risk to children; and

(c) clarify criteria for evaluating proposed changes to existing regulations.

18. EPA should work with the Chemical Specialties Manufacturers Association to reform/streamline registration of antimicrobial and pesticide products to assure these products are available to protect children and others from exposure to microorganisms and insect borne diseases.

19. EPA should review standards and compliance programs related to drinking water to assure drinking water is free from microorganisms caused by inadequate disinfection.

20. EPA should promote effective cleaning products as part of its indoor air quality program and its child health initiative.

21. We recommend that EPA review and discourage publications that recommend that consumers formulate their own household cleaning products, which could increase environmental risks to children and others.

22. The Network strongly urges the Agency to take a broader view of what

is considered a "standard" for the purposes of this review.

23. The Agency needs to review how its risk assessments are conducted, the default assumptions used, and change them to appropriately reflect pediatric issues.

24. The Agency should evaluate the standards it is considering for review in large part based on assumptions inherent in the risk assessments (e.g., did the exposure estimates account for children's behavior; did toxicology studies include fetal and neonatal exposure; did the standard consider appropriate toxicological endpoints?)

25. The Agency needs to look at chemicals by class or by mechanism of action as "one standard" rather than a chemical-by-chemical approach.

26. The Agency should use this exercise as an Agency-wide education opportunity to further the goals of the child health protection initiative and to expedite the universal adoption of similar practices throughout the Agency.

27. The five standards selected should be from a variety of different program offices or across program offices.

28. The Agency should move expeditiously, set aggressive deadlines and follow them.

29. The Agency must review all standards and should publicly announce the process and schedule by which it will conduct the review.

30. Persistent toxic substances are too dangerous to the biosphere and environment, deleterious to the human condition and should not be released in the environment in any quantity.

31. Risk assessment and chemical-by-chemical regulation undermine pollution prevention efforts—elimination of persistent toxic substances should not be subject to a risk benefit calculation.

32. Although fluoride is often not considered a toxic substance, it is suspected to impact the mental development of children.

33. We propose addressing the cumulative effects of various pathways of exposure.

34. The specific recommendations are based on problems evident in our urban environments—children of these families may be especially vulnerable because of conditions associated with poverty:

(a) Persistent toxins in the drinking water supply (cadmium and compounds, chlordane, DDT/DDE, Dieldrin, Hexachlorobenzene, a-HCH, lead and compounds, Lindane, Mercury and compounds, PCBs, Polycyclic organic matter (POM), TCDD (dioxins),

TCDF (furans), Toxaphene, Nitrogen compounds);

(b) Volatile organics found in ambient air in urban areas;

(c) Lead in soil—there appear to be conflicting standards among the EPA, HUD, and U.S. Public Health Service regarding lead in soils. A universal standard would be helpful in the battle against child lead poisoning. The standards for lead do not address multiple source exposure;

(d) Aeroallergens in the household—currently no standard—EPA may want to be more proactive with the increase in childhood asthma;

(e) Fish consumption advisories—relative to mercury and PCBs current standards do not address bioaccumulation effects in children; and

(f) Common pesticides and herbicides frequently used in lawn care.

35. EPA should consider the risk of arsenic exposure to children through arsenic treated wood.

36. Children may be exposed to arsenic from treated wood products by direct hand to mouth contact with the wood or from arsenic contaminated soil under wooden decks. Soil may become contaminated by leaching, deterioration of the wood, or sawdust generated during construction.

37. Arsenic is linked to skin and bladder cancer.

38. Research links arsenic to lower IQ's.

39. 50,000,000 pounds of arsenic are imported into the U.S. every year for treating lumber.

40. Millions of treated decks and playscapes leach arsenic into the soil and children are exposed via direct contact with the wood and the soil.

41. EPA is inconsistent in the application of its policies and regulations (i.e., safety factors to protect children's health.)

42. If arsenic were evaluated today it would not stand up to the risk calculations under FQPA.

43. The arsenic MCL is 17-fold greater than the triazine MCL even though arsenic has an estimated 100-fold greater NOAEL than triazine and is a class "A" human carcinogen.

44. There is no explanation for a decade-old delay in acting to lower the arsenic MCL which may have caused harm to an entire generation of children exposed to imported arsenic in a variety of ways that are unique to children's active daily lives.

45. We propose that EPA review the standards for lead poisoning in the following areas: paint, soil, dust, and drinking water.

46. All public water systems shall be fluoridated to improve the dental health of children.

47. All public and private water system/supplies shall be safe for children to drink.

48. Children shall reside in adequate housing that is not dangerous, crowded or cost more than 30% of family income.

49. Children shall not be exposed to high concentrations of lead in their environment.

50. Recommends systematically reevaluating all standards.

51. Hope that standards are selected, reviewed, and adopted with respect to their impact at the local level.

52. Suggest that EPA consider standards for asthma hazards such as mites, mold, and cockroaches.

53. The National Center for Lead-Safe Housing (the Center) has worked with EPA in the development of standards for lead. The person submitting the comment also indicated that the Center is broadening its mission to include environmental hazards and hopes to work with EPA if the agency decided to work on standards related to children's respiratory diseases.

54. "Standard" as described in the FRN is too restrictive—all EPA standards (including existing and technology based), guidelines (risk assessment and toxicological), and unregulated threats should also be considered.

55. The following five proposals address the solicitation of the FRN but should not be seen as an endorsement of the EPA strategy, but rather an illustration of the types of threats from which children are not well protected:

(a) Review of tolerances for all pesticides which act via inhibition of acetyl cholinesterase;

(b) Review of tolerance for all triazine herbicides found in drinking water in the U.S.;

(c) Review of drinking water standards for microorganisms and disinfection byproducts;

(d) Review of all standards designed to protect children from environmental lead exposure, and issuance of the Title X lead hazard disclosure rules; and

(e) Review of the SO₂ air quality standard to protect children with asthma, issuance of standards for acid aerosols and diesel exhaust, and vigorous implementation of the new standard for ozone and fine particulates to protect the asthmatic children.

56. A variety of environmental influences are risks to children's health including intake by pregnant mothers of alcohol, cigarettes, and controlled substances. Other factors that affect children's health include diet and access to adequate medical care.

57. We encourage EPA to examine those standards which give exposure to lead, radon, and asbestos.

58. The Lead Industries Association is concerned that the mention of lead exposure in the FRN as a children's health problem gives the impression that one or more lead regulations should be tightened to adequately protect children's health. From the outset lead regulations have been developed to protect children's health.

59. Existing lead regulations are protective of children's health and should not be included in the Committee's list of regulatory standards needing reconsideration and downward revision. Children's blood lead levels are declining under the existing lead regulatory regime and there is no need or justification for costly, more stringent regulation.

60. Many serious health problems afflict our nation's children—including the need for universal immunization and prenatal care, reduction of infant mortality rates, and threats from the rising risk of HIV infection, abuse, neglect, drug use, and violence.

61. The use of water containing the action level for copper would more than double the amount of copper in an infant's diet. Infants less than two years of age have a limited ability to excrete copper.

62. Children who consume more than two servings of fish per week can develop elevated blood mercury levels.

63. Instead of a drinking water standard, EPA has a lifetime health advisory for ammonia-nitrate based on the taste/odor threshold instead of a health-based effect. Studies associate ammonia ingestion with alteration in the gastric mucosa and risk of gastric cancer neurotoxicity.

EPA Response to Federal Register Document Comments

EPA believes all the comments had merit, however, not all of them were directed at the question we asked, i.e., to identify existing standards that were worthy of reevaluation to better protect children's environmental health. Nor did they all address issues within the purview of EPA. Some of those who commented asked us to reevaluate recently promulgated standards, which we had specifically excluded from coverage in the document. In addition, standards currently in litigation were determined by EPA to be inappropriate for reevaluation at this time. However, EPA did consider all comments that recommended existing standards for reevaluation. Further, all the comments were referred to the CHPAC work group charged with submitting

recommendations to the Agency for re-evaluating existing standards.

In many instances, EPA found that there was no new information sufficient to support a decision to revise an existing standard. For example, in the case of dioxin, the Agency is revising its risk assessment, but that information is not yet available. When it is available, the Agency may re-evaluate existing standards if that is indicated by new data. Similarly, EPA is engaged in a large, multi year research and data collection effort to better define health risks, occurrence and exposure, and treatment effectiveness for microbial contaminants and disinfection byproducts in drinking water. Research areas include reproductive and developmental effects, and sensitive sub population exposures. The final Stage I Rule for Disinfectants and Disinfectant By Products was issued on December 16, 1998. A health assessment for fetuses, infants and children was conducted to support the rule.

In some cases, EPA is already engaged in re-evaluating standards identified in the public comments. Examples include the reevaluation of the organophosphate and triazine pesticides. The Agency is required by the Food Quality Protection Act (FQPA) to re-evaluate all pesticide tolerances, basing new decisions on aggregate exposures and common mechanisms of action. The FQPA requires use of an additional uncertainty factor to protect children unless reliable data demonstrate the additional factor is unnecessary. Further, the Agency issued on November 16, 1998, a Draft Multimedia Strategy for Priority Persistent, Bioaccumulative, and Toxic (PBT) Pollutants which includes an Action Plan for Mercury. The goal of the strategy is to further reduce risks to human health and the environment from existing and future exposure to priority PBTs such as mercury, dioxins, furans, chlordane, DDT, dieldrin, toxaphene, hexachlorobenzene, alkyl-lead and PCBs. Further a draft rule for identifying lead hazards in dust, soil and paint was issued on June 3, 1998.

In summary, EPA's decisions to reevaluate the Chloralkali NESHAP (mercury); the implementation and enforcement of the (Farm) Worker Protection Standards; pesticide tolerances for the organophosphates (chlorpyrifos, dimethoate, methyl parathion); atrazine (pesticide tolerance and MCL); and to review indoor and ambient air quality as they relate to asthma are based in part and are supported by recommendations received through the **Federal Register** document and from the Children's Health Protection Advisory Committee.

Attachment B—CHPAC Screening Criteria to Select Rules for Re-Evaluation (2/24/98)

Children's health protection would be strengthened if these regulation-based standards, policies or rules were re-evaluated and subsequently changed because:

A. Children's health was not considered in the original development of the standard, such as:

- Exposure estimates did not adequately account for children's behavior;
- Toxicology studies did not include fetal, neonatal, and early childhood exposure; or
- The standard did not consider the full range of appropriate toxicological endpoints for fetal, neonatal, and early childhood exposure.

B. Children's health was considered but new information or data suggest the standard does not adequately protect children. The new information or data, based on peer-reviewed science, may include considerations such as:

- Descriptions of adverse health effects in children;
- Increased susceptibility for children to specific substances because of their unique physiology;
- New understanding of routes of exposure to children;
- Mechanisms of exposure that better reflect children's activities;
- Whether, and the extent to which the regulated substance is persistent and bioaccumulative;
- Improved methodologies for evaluating human health risks;
- Epidemiology studies;
- consideration of disproportionate exposures to sub-populations (e.g., geographic, racial);
- Toxicity studies;
- Environmental monitoring studies;

or

C. Major threats to children's health will be addressed such that a change in the regulation will result in a significant improved health outcome for children:

- Severity of health outcome of concern;
- Number of children adversely affected;
- Substances to which children are highly exposed; or
- Substances to which children are highly susceptible.

D. Revisions will have broad precedent setting impacts in terms of changing the procedures, guidelines, and overall culture of the Agency to include children's environmental health issues in all aspects of its work.

E. Children's health issues could be assigned higher priority for rules

selected (e.g., how revisions to the rules fit Agency existing plans/schedules).

F. Rules will span a diverse list of hazards (e.g., variety of substances and/or media programs) and a variety of health endpoints (e.g., cancer, non-cancer).

G. Rules whose effectiveness in protecting children's health would be greatly enhanced by revisions that facilitate its implementation or improve its enforceability.

Dated: January 26, 1999.

E. Ramona Trovato,

Director, Office of Children's Health Protection.

[FR Doc. 99-2447 Filed 2-2-99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-51922; FRL-6060-2]

Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical to notify EPA and comply with the statutory provisions pertaining to the manufacture or import of substances not on the TSCA Inventory. Section 5 of TSCA also requires EPA to publish receipt and status information in the **Federal Register** each month reporting premanufacture notices (PMN) and test marketing exemption (TME) application requests received, both pending and expired. The information in this document contains notices received from December 17, to December 31, 1998.

ADDRESSES: Written comments, identified by the document control number "[OPPTS-51922]" and the specific PMN number, if appropriate, should be sent to: Document Control Office (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Rm. ETG-099 Washington, DC 20460.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: oppt.ncic@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 5.1/6.1 file format or ASCII file format. All