Responses to Comments on Proposed Permanent Rules Relating to Health Risk Values: Minnesota Chamber of Commerce Comments on the proposed rule.

1. Page 160, under "Table of Chronic HRVs, G. Benzene (71-43-2): The proposed rule and the SONAR present a range of values for this compound. Neither document explains how this range was developed, why the range is included or how to implement a range (vs. a single HRV value).

The HRV for benzene was developed using the portion of the U.S. EPA IRIS database that presents a range of cancer risk associated with an inhalation exposure to benzene. This fairly unique approach is based on the fact that the U.S. EPA in its analysis of the available information concludes "the set of risk estimates falling within this interval reflects both the inherent uncertainties in the risk assessment of benzene and the limitations of the epidemiologic studies in determining dose-response and exposure data." MDH chose to develop a HRV for benzene that reflected these uncertainties and limitations. Our intent was to indicate to risk managers that there was an additional level of uncertainty when estimating the risk associated with inhalation exposure to benzene. From a practical point MDH realizes that the most frequent approach, and indeed the prudent approach from a public health protection standpoint, would be to use the lowest estimate in a quantitative assessment of risk.

Action: No change will be made.

2. Page 164, under "Table of Chronic HRVs JJ. Naphthalene (91-20-3): The committee agreed and the SONAR states that a cumulative uncertainty factor will not exceed 1,000. However, the HRV for naphthalene contains an uncertainty factor of 3,000. This HRV should be deleted (see SONAR comment # 15).

Although the MDH HRV external advisory committee supported a position of limiting uncertainty factors, the SONAR does contain a qualifying statement regarding uncertainty factor limitations. It has been a priority for the MDH, when developing HRVs, to use the best information available to derive these numbers. Because uncertainty factors greater than 1,000 in general indicate either that there are limited data, or that the data available are of poor quality, MDH has, **as a general policy**, developed HRVs from data sets where the resulting uncertainty factor is 1,000 or less. In the case of naphthalene staff felt that because of the importance and wide use of this chemical and despite the limited amount of data a HRV should be proposed. Recently, however, the National Toxicology Program has completed a cancer bioassay with naphthalene that provides clear evidence that naphthalene is carcinogenic in rats. This information will be undoubtedly be used for a re-evaluation of a health based value for naphthalene and it likely that a new naphthalene number, based on carcinogenicity, will soon be available on the U.S. EPA's IRIS database. This raises the likelihood that MDH would have to revise its HRV for naphthalene in the not too distant future.

Action: MDH will withdraw its proposed HRV for naphthalene; however, by withdrawing this number MDH is in no way limiting the future use of a cumulative uncertainty factor greater than 1,000 if circumstances make it necessary.

3. Page 174, under "Table of MHRVs for Multimedia Exposure to Air Toxics", F. Metylmercury (22967-62-6). To dispel any potential confusion about this application and the other forms of mercury, either the rule or the SONAR or both should include a statement that this rule does not apply to mercury ions and elemental mercury and its associated pathways.

This is an application issue. The MHRV was developed for methylmercury. This organic form of mercury has a CAS number distinct from elemental and other forms of inorganic mercury. The chemistry and behavior of these distinct forms of mercury in both the atmosphere and tissues of organisms make it inappropriate to use the MHRV for methylmercury as a surrogate for other forms of mercury. The MHRV for methylmercury should not be applied to elemental and other inorganic forms of mercury. MDH, because of the public health importance of all forms of mercury, intends to develop HRVs for individual mercury compounds when sufficient information is available.

Action: No change will be made.

4. Page 178, under "Procedure for Determining Cancer Index for Simultaneous exposure to Multiple Carcinogens" Subpart 2.B. and Subpart 3.d., the proposed rule makes reference to "cumulative HRV and cumulative MHRV". The same references are found in section 4717.8500 Procedure for Determining Hazard Index for Assessing Simultaneous Exposure to Multiple Noncarcinogenic Toxicants, Subparts 2.E. and 3.D. This term is not defined in the proposed rule. A definition should be added stating that a cumulative HRV or cumulative MHRV is derived using emission rates from a specific facility, source or site.

Action: the following definitions for cumulative HRVs and cumulative MHRVs will be included in the rule.

A cumulative HRV is a HRV calculated by summing the hazard quotients of chemicals sharing a common endpoint. A hazard quotient for a particular chemical is calculated by dividing the measured or modeled ambient air concentrations for a chemical by the HRV for that chemical. The equation used to calculate a cumulative HRV or hazard index for noncarcinogenic effects of chemicals is found in rule part 4717.8600. The equation used to calculate a cumulative HRV or cancer index for carcinogens is found in rule part 4717.8550.

A cumulative MHRV is a MHRV calculated by summing the hazard quotients of chemicals sharing a common endpoint. A hazard quotient for a particular chemical is calculated by dividing the measured or modeled ambient air concentrations for a

chemical by the MHRV for that chemical. The equation used to calculate a cumulative MHRV or hazard index for noncarcinogenic effects of chemicals is found in rule part 4717.8600. The equation used to calculate a cumulative MHRV or cancer index for carcinogens is found in rule part 4717.8550.

MDH cannot specify that the cumulative HRV or cumulative MHRV will be derived "using emission rates from a specific facility, source, or site." This is an application issue.

MDH, in reviewing the Chamber's "Comments on the SONAR", identified two additional comments that are actually comments on the on the rule.

21. Page 24, under "Acute HRV timing issues", third bullet: It was our understanding that when the exposure period in the published toxicity study was between 0.5 and 2 hours no time adjustment would be made. Time adjustments should be made for exposure periods of 2 to 8 hours only.

The Chamber is correct. Rule part 4717.8500, Subp. 3 which includes the method for correcting exposure times between 30 minutes and 1 hour a time will be deleted. This change will affect the HRVs for eight chemicals; chlorine, hydrogen chloride, hydrogen cyanide, hydrogen sulfide, nickel and nickel compounds, nitric acid, 1,1,1-trichloroethane, and xylenes.

Chemical	Previous HRV ($\mu g/m^3$)	Revised HRV ($\mu g/m^3$)
Chlorine	150	290
Hydrogen chloride	2,100	2,700
Hydrogen cyanide	300	700
~~Hydrogen sulfide~~	~~80~~	~~200 *~~
Nickel and nickel compounds	6	11
Nitric acid	86	130
1,1,1-Trichloroethane	68,000	137,000
Xylenes	22,000	44,000

Action: The HRVs for chlorine, hydrogen chloride, hydrogen cyanide, nickel and nickel compounds, nitric acid, 1,1,1-trichloroethane, and xylenes in the rule will be corrected.

* During MDH's reanalysis of the HRV for hydrogen sulfide it became apparent that additional issues needed to be resolved before the agency could propose an acute HRV for this chemical. MDH has therefore withdrawn the proposed HRV for hydrogen sulfide from the rule.

Page 28, under "Reproductive/Developmental Effects": This was not discussed in the committee. As presented in this section, there are evidently two categories of reproductive endpoints. The first is adverse effects on either the male or female reproductive system when exposure occurs after birth; the second is subsequent adverse reproductive effects in an individual caused when the exposure occurred in utero. These categories are grouped together and the text in this section is confusing. We suggest that only chemicals in the first category, exposure after birth, should be designated reproductive effects. Chemicals in the second category, exposure in utero, should remain as developmental toxins. The toxic endpoints in the rule should only be designated "reproductive/developmental" if the critical studies on which the HRV is based indicate both types of responses at very similar or identical doses, otherwise either one or the other designation should be used.

This revision will help in two ways. First summing the concentration-HRV ratios to develop a toxic endpoint–specific cumulative HRV will be more accurately performed; second the proposal to consider developmental HRVs as ceiling values is more scientifically sound. The reproductive systems in our body have a variety of protective mechanisms or repair ability; therefore, short-term exposure damage, if it occurs, is unlikely to lead to a permanent lesion. The contrary is true for effects on the developing embryo or fetus, which do need maximum protection.

The term "Reproductive/Developmental Effects" refers to the changes that result from an *in utero* exposure to a chemical and therefore includes endocrine disrupting chemicals that cause changes in the reproductive systems of developing embryos and fetuses. This terminology is consistent with the California acute RELs. With the current research interest in endocrine disrupters it is likely that a number of chemicals will be identified that have the ability to alter the normal development of the reproductive system, but whose effects may not be apparent until the impacted individual reaches sexual maturity. It is important that HRVs for these chemicals be considered ceiling values. These reproductive/developmental effects are distinct from the reproductive effects that occur following post-natal exposures and should not be included in calculation of hazard index for reproductive toxins.

Action: No change will be made.

Responses to Comments on Proposed Permanent Rules Relating to Health Risk Values: <u>Minnesota Pollution Control Agency</u> Comments on the proposed rule.

Specific issues raised by the MPCA

1. The MPCA will continue to use other data sources for health benchmarks in addition to the HRVs.

MDH realizes it would be unrealistic to assume that the HRV rule, in its initial form, could provide all of the health-based values that should be used to protect the public from

chemicals emitted to air. However, MDH does expect, that, when available, Health Risk Values will be used by state agency programs as the health based criteria for management of air pollutants. If a HRV exists, the value, for the purposes of permitting, should be considered the best available and its use should not be questioned by the involved parties.

MDH also recognizes that as new information becomes available there may be a need to reexamine a HRV. If and when this becomes necessary, MDH staff will examine the available data and determine whether it is appropriate to use a value other than a HRV until the existing HRV can be modified. Any such change will be announced in a formal memorandum released by the department. It is expected that this will not be a common occurrence.

As stated in the SONAR that accompanies the HRV rule Athe initial list of HRVs is not inclusive and the absence of a chemical from the HRV list does not imply that there are no health risks associated with the emission of that chemical to air@. MDH recognizes that there are health based values other than HRVs that have been generated by federal and state agencies, and that some of these values are of sufficient quality that their use in protecting public health would be appropriate. However, because the ultimate authority for development and adoption of rules to preserve the public health lies with the Commissioner of Health, MDH feels that it is important that any value proposed for use by an agency or its clients be examined by appropriate MDH staff before it is used to regulate emissions.

Evaluation of all available health based values is precluded by staff limitations therefore, the MDH proposes the following regarding the development and/or use of non-HRV health based values. Values suggested to the Department by other agencies or regulated parties should come from one of the following sources (listed in order of preference); the U.S. EPA IRIS database, the California RELs and cancer values, U.S. EPA HEAST values, and ATSDR minimal risk levels. If a non-HRV value from one of the above sources becomes important in an agency review, e.g., it would be a risk driver in an air toxics review, MDH staff will review the number and determine if the value is appropriate for site specific use. If there is a critical need for a health based value for a particular chemical and none is available, MDH agrees to review information provided to staff by other agencies or the regulated community to determine if an appropriate site-specific value can be developed and used. MDH recognizes that until interim values are promulgated they do not carry the authority of rule, however, in the interest of public health protection the Department considers the use of MDH approved interim health-based values appropriate.

2. The MPCA encourages the MDH to develop processes for updating HRVs.

The MDH understands the concern expressed by the MPCA regarding the frequency for revisions and the mechanism that will be used in the interim. The absence of such information in the rule or the SONAR was not an oversight, and in fact earlier drafts included attempts to address these issues. MDH feels that this particular issue, though important, lies outside the scope of the current rule, and suggests that since it lies outside

the present rule the most reasonable way to approach the issue is to develop memoranda of agreement (MOA) between MDH and the agencies that will be applying the HRVs. Mechanisms for the development and use of interim health based values will be included in this MOA.

Although MDH staff actively monitor the available literature for new data and techniques, there is a possibility, however remote, that there may be information that hasn't yet come to the attention of staff. The MDH will gladly review any information provided by the MPCA, other agencies, or other stakeholders.

3. HRV Characterization with Respect to the Certainty of Protection.

The language "unlikely to cause a health effect to the general public" implies a measure of uncertainty in the process of developing the HRVs – it is naive to believe that absolute safety can ever be achieved, let alone guaranteed. The techniques used to develop the HRVs are, by design, conservative (not *generally* conservative as suggested by MPCA staff) with the intent that it is more appropriate from a human health standpoint to be overprotective than is to be underprotective.

(a) Expression of Certainty

When health-based values are developed all of the available toxicity information for all end-points is examined. Prudent public health policy dictates that the most sensitive endpoint from the studies is used for the development of the HRV. This is based on the assumption that prevention of exposures that would trigger the most sensitive effect will afford protection of effects that would be expected from larger exposures. We can say that "exposures to chemicals at or below the HRVs present minimal risk human health" *for the toxic endpoints listed in the rule* **and all of the endpoints that occur at higher exposure concentrations**. We cannot say with certainty that another, perhaps as yet unrecognized or uncharacterized endpoint such as endocrine disruption may not be more sensitive, but with current risk assessment tools we do not protect against unobserved risks. Any movement away from these traditional approaches would be policy and not based on science. Current risk assessment models do not allow us to protect from "unseen" risks.

MDH does recognize that if quantitative information for other endpoints for a particular chemical is available it could be useful for additivity calculations during the various application processes. This was discussed during MDH's external HRV workgroup meetings and the workgroup decided that the rule should list a single HRV value. Because of the conservative assumptions inherent in the techniques used to develop cancer potency slopes or unit risks for carcinogens, it is typical that an HRV developed using cancer as an adverse endpoint will be lower than an HRV for the same chemical based on an alternate endpoint. MDH policy is to use the lowest defensible value for the HRV. Here again, MDH's assumption in these cases is that any number based on a cancer endpoint will be protective for less sensitive endpoints. MDH did, however, agree

to collect information on alternate endpoints when it is available and provide it to agencies in the form of guidance documents or fact sheets.

(b) Toxic Endpoints

MPCA staff have suggested that MDH "flag" chemicals in the rule as a means of indicating when available toxicity information for chemicals is incomplete. MDH staff suggests that flagging chemicals that do have complete data sets would make more sense. It would certainly result in fewer chemicals being flagged.

MPCA staff has presented an argument based on the HRV for diesel exhaust that suggests that MDH should provide some notation if a chemical has a toxic endpoint for which no quantitative estimate of risk can be generated. This comment is in no doubt based on previous discussions where MDH staff, because of data limitations, were not able to support a proposal by MPCA staff to use a cancer slope for diesel exhaust developed by the California EPA.

In the specific case of diesel MDH feels that it is entirely likely that diesel exhaust is carcinogenic. However, because the composition of diesel exhaust is highly variable, and because the studies attempting to characterize the risk associated with these exhausts are lacking, a quantitative estimate of risk is not possible. It appears that MPCA staff is suggesting that the HRV may not always be protective, but we have no way of determining whether or not this is the case. Any attempt to quantitate the risk from diesel exhausts would have to be based on policy driven techniques and decisions. Such arbitrary approaches as a component of the risk assessment portion of the process are not supported by the guidelines produced by either the U.S. EPA or the MDH external HRV workgroup. Such approaches are, and should remain, a portion of the risk management process. MDH feels that the appropriate approach would be to develop guidance regarding MDH's policy decisions that would remain separate from the rule and be clearly labeled as guidance for risk managers. As previously mentioned, MDH has agreed to provide this information in separate documents.

4. Clarification of the Avoidance of Cumulative Insults for Acute HRVs.

MDH understands that the current position of MPCA staff is that "guidance of this nature is an application of HRVs and is beyond the intended scope of the rulemaking". This is a change in MPCA's position since the section "Avoidance of Cumulative Insults for Acute HRVs" was included in response to an earlier request by MPCA staff. It has, however, been brought to the attention of MDH that this guidance has been misinterpreted by some members of the regulated community to mean that MDH is suggesting that periodic exposures to chemicals at concentrations higher than the HRVs should be permissible. This misunderstanding is unfortunate. The guidance was included to indicate to risk managers that *in addition* to the risks associated the acute exposure of individuals to concentrations of a chemical higher than HRVs, there is a very real possibility that subchronic or chronic impacts can occur with repeated exposures to levels of chemicals higher than the acute HRVs. This is why the term "cumulative insults" was used. MDH

sees this as an argument against repeated exposures to chemicals that can have acute impacts. As with all guidance provided by the MDH, MPCA is free to chose whether or not to use it.

5. Chromium VI

MPCA staff are correct in their analysis of the EPA's Toxicological Review.

Recalculating the unit risk is not possible. Given that ratio of chromium III and chromium VI will vary from one site to another any such ratio would have to be site specific. MDH staff agrees that there is a chance of underestimating the risk from chromium emissions if the emission estimates are for chromium VI rather than total chromium. Because the IRIS database specifically calls the unit risk an estimate for chromium VI (and uses the CAS number for chromium VI), MDH prefers to remain consistent with the U.S. EPA. MDH will, however, provide guidance in the form of a memo that advocates the use of the HRV for chromium VI for total chromium emissions.

6. Revisions to the Dioxin HRV.

MDH will withdraw the MHRV for dioxin (2,3,7,8-tetrachlorodibenzo(p)dioxin; CAS number 1746-01-6). When the U.S. EPA has completed its reassessment MDH will propose a MHRV for dioxin.

7. The use of REL terminology

MDH intends to use the California RELs as presented in the SONAR. The MDH is aware that the California EPA does not include cancer values in their RELs; however, because MDH has chosen not use cancer values produced by the California EPA in the current version of the rule, no mention is made of these values. If MDH uses cancer numbers from California in a future revision of the HRVs the necessary information will be included at that time.

8. Characterizing Cancer Risk Estimates

Probability is a *may* by definition – it is a likelihood not a certainty. The only certainty is a probability of one.

9. Correct Error Referencing Equations for HRVs

The error has been corrected.

10. Clarification of Descriptions of Chemicals as Carcinogens vs. Noncarcinogens

The change has been made.

11. Clarification of the Units for Calculating Cancer Endpoints

The change has been made.

Responses to Comments on Proposed Permanent Rules Relating to Health Risk Values: General responses to the Sierra Club, the Women's Cancer Resource Center, and Representative Jean Wagenius who made similar comments regarding the HRV rule.

Additional lifetime cancer risk

The commenters listed above have questioned the appropriateness of MDH's use of 1 in 100,000 as the additional lifetime risk to calculate HRVs for chemicals that cause cancer. The same commenters have suggested that 1 in 1,000,000 would be more protective of sensitive individuals particularly children.

As discussed in the SONAR the equations used to develop HRVs for carcinogens require that a level of additional risk be selected for a calculation of an acceptable level of chemical in air. Values for additional lifetime risk (the terms acceptable or negligible lifetime risk have also been used to refer to the same value) are not science based, rather they are conventions developed by policy makers who use various endpoints, such as the risk of natural disasters, to establish a risk level to be used in the protection of the general population. As pointed out by the commenters, MDH's policy is to use 1 in 100,000 (1×10^{-5}) as the additional lifetime cancer risk. MDH currently makes no judgment regarding the "acceptability" or "negligibility" of 1 in 100,000 as an additional lifetime risk of cancer.

Despite the fact that the derivation of numbers such as an additional lifetime risk relies heavily on policy decisions, available information can be used to analyze the approach and determine whether or not it is working as intended. Public health policy dictates that, in the face of uncertainty, conservative approaches be used so that any errors in the process will result in an over protection of health rather than an under protection. This is the foundation of risk assessment in general and cancer risk assessment in particular. As explained in the SONAR, when modeling data from cancer studies, ***a number of conservative assumptions are made. One of the major assumptions made is that carcinogenic effects of chemicals observed with the high dose exposures used in cancer bioassays are indicative of changes that would occur at much smaller doses. A good deal of the available evidence suggests that cells respond very differently to large concentrations of chemicals than they do to smaller ones. Modeling of results from high dose exposures are, therefore, more likely to overestimate the risk of low dose exposures than to underestimate it. Another*** conservative assumption made is that the dose response curve for carcinogens is linear and has no threshold. Based on such a model there is some level of risk, no matter how small, associated with exposure to any amount of a carcinogen. Current research has shown that this is unlikely except for a few direct acting carcinogens. This means for a majority of carcinogens, numbers based on linearized non-threshold modeling will overestimate cancer risks and that the true risk

from exposure lies somewhere between the number generated and zero. The newly proposed U.S. EPA guidelines for cancer risk assessment recognize these factors and, where additional data are available, provide alternate methods for developing health-based numbers for carcinogens.

Because of the conservative nature of the modeling used in developing cancer potency slopes and unit risks, health protective numbers that have cancer as an endpoint are typically much more protective than those based on noncancer endpoints. In the case of non-cancer endpoints, MDH policy is that the total uncertainty factor used to develop HRVs in general will be no larger than 1,000. ***The techniques used to develop cancer numbers using the linearized non-threshold model for carcinogens incorporate two default approaches that are public health protective. The first is the use of the statistical limit for a population response rather than a modeled data point to add a level of conservatism by accounting for experimental variability. The second is the use a scaling factor of body weight to the 0.75 power to adjust for the differences in metabolic rates between species. The use of these default approaches results in margins of safety that are often comparable to uncertainty factors of 10,000 for noncarcinogens.***

The conservative nature of cancer numbers is also evident when comparing an additional lifetime risk level to the background rate of cancer. In Minnesota the current risk of a male developing cancer during his lifetime is about 1 in 2 or 50 percent. The exposure to a chemical at a concentration that presents a 1 in 100,000 additional lifetime risk increases the potential for cancer developing in the average Minnesota male to 1 in 1.99996 or 50.001 percent during a 70 year lifetime. The Sierra Club comments predict that an additional risk of 1 in 100,000 could result 49 additional cases of cancer in a lifetime (or 0.7 cases per year). Comparing this to the 20,000 cases expected to be diagnosed in Minnesota each year suggests that this upper-bound estimate of risk suggests the possibility of a maximum increase in cancer incidence of roughly 4/1,000ths of a percent.

Arguments similar to these have been used to suggest that the techniques used to estimate cancer risk are too conservative. This is not the intent of the MDH. These points are made not to suggest that cancer numbers are too conservative, ***but that current research indicates that they don't need to be made more conservative to protect public health.***

It is the judgment of Minnesota's state agencies that, given the current state of knowledge, the use of 1 in 100,000 additional lifetime risk provides a scientifically defensible level of protection. However, MDH does recognize that the notion of what constitutes an "acceptable risk" will vary depending on a number of factors, and feels that the question of the appropriate level of additional lifetime risk, and a potential change from the Department's current policy, is one that should be addressed. ***However, because the selection of an "acceptable risk" is a policy question of considerable importance to all Minnesotan's, it is logical that the question should be addressed by a stakeholder group and that the ultimate decision should be made with input from both the stakeholder group and the legislature.***

Children's Environmental Health

The commenters listed above have questioned whether the HRVs in their present form provide an adequate level of protection for children. There is an increasing awareness in the risk assessment community that children, for a number of reasons, may be uniquely susceptible to the toxicity of chemicals including environmental pollutants. This is an active area of investigation by the research and regulatory communities. When considering the adequateness of HRVs it is important to remember that the development of health based values to be used in protecting human health is a conservative process. The consideration of the variation that results because of differences in individual susceptibility is fundamental to the risk assessment process. It uses one uncertainty factor to account for the fact that children and adults or sick and healthy adults do not always react to chemicals in the same way, and another to allow for the fact that humans do not necessarily respond to chemicals in the same way that experimental animals do. The development of numbers using cancer as an endpoint also uses a number of conservative approaches, including the assumption that all chemicals that cause cancer behave as though there were no thresholds for their effects. A major default assumption is that, from a public health standpoint, it is better to use techniques that overestimate the risk inherent in exposure to a particular chemical than it is to underestimate it.

Several examples of an increased sensitivity of children exist. For mercury, lead, and the PCBs there is a 3-5 fold increased sensitivity of developing fetuses and young children to these compounds when compared to adults. In each of these cases the 10x uncertainty factor applied to account for intraspecies or individual variation would be adequately protective of children.

MDH programs have taken action to protect developing fetuses and young children from materials such as mercury, lead, and the PCBs. In the 1980s MDH developed health based numbers for PCBs and mercury that were designed to be protective of the developing nervous system and used to offer fish consumption advice for pregnant women and young children. MDH's lead surveillance program actively monitors at risk children for elevated blood lead levels and provides for intervention when children with high blood levels are discovered.

Based on the above examples, the conservatism built into the risk assessment procedures, and the current state of available science, MDH feels ***its programs*** and the health based values, including the HRVs, it has developed are protective of all age groups. However, as a portion of MDH's duties to protect the public's health, MDH will closely monitor research in the area of children's health and incorporate any additional information that becomes available into the HRV process. Existing HRVs will also be modified as needed.

Responses to Comments on Proposed Permanent Rules Relating to Health Risk Values: Sierra Club Air Toxics Campaign comments on the proposed rule.

MDH thanks the Sierra Club Air Toxics Campaign, the Minnesota Center of Environmental Advocacy, Minnesotans for an Energy-Efficient Economy, Indigenous Environmental Network, Minnesota Children's Health Environmental Coalition, and the Izaak Walton League Minnesota Division for their letter of support for the promulgation of the proposed rules establishing and agrees that it is an important first step in preventing adverse health effects from chemicals emitted to air in Minnesota.

In general comments the Sierra Club suggests:

> **- The proposed Health Risk Values incompletely protect the health of the citizens of Minnesota.**
>
> **- The proposed Health Risk Values fail to completely conform with recently-enacted State law requiring that air quality standards established by the Commissioner of Health must include a reasonable margin of safety to protect the health on infants and children.**

Comments addressing additional lifetime cancer risk and children's health are presented above in "**Responses to Comments on Proposed Permanent Rules Relating to Health Risk Values: General responses to the Sierra Club, the Women's Cancer Resource Center, and Representative Jean Wagenius who made similar comments regarding the HRV rule."**

Chronic Health Risk Values should be changed to protect Minnesota citizens from long-term exposure to toxic chemicals, including those identified in the California rules cited by the Health Department.

The Sierra Club suggests that MDH incorporate numbers such as the California RELs into the current version of the HRV rule. It is assumed that the request is for an adoption of the California RELs by reference. The guidelines for development of HRVs established by the MDH in consultation with the HRV external work group require that MDH evaluate the available scientific information and use currently accepted risk assessment techniques to develop the HRVs.

Using the above mentioned guidelines MDH analyzed the acute RELs and found the information provided for a number of chemicals suitable for developing acute HRVs. However, there are several acute RELs that were developed using information that, according to the HRV guidelines, is unsuitable for the development of acute HRVs. The fact that a number of California RELs were developed using unsuitable information would preclude an adoption by reference of the California RELs.

As with the acute guidelines, MDH uses criteria developed with the input of the external HRV work group to produce chronic HRVs and MHRVs. As yet, MDH has not opportunity to completely examine the California chronic RELs. While it is likely that the information provided in their documentation will be adequate for the development of HRVs, a preliminary analysis has indicated that MDH's chronic guidelines will preclude the development of HRVs from the information and techniques used to develop several chronic RELs.

As stated in the SONAR it is the intent of the MDH to periodically review and update the HRV rule ultimately achieving the Department's goal of where possible developing health protective values for chemicals or substances emitted to air that have the potential to produce a human hazard. It is the opinion of the MDH that as a matter of prudent public health policy it is better to promulgate a rule that includes the HRVs produced to date than to delay the rule until numbers can be developed for more chemicals.

The Sierra Club suggestion that because no HRV exists the public is not being adequately protected reflects a misunderstanding of how health based values such as the HRVs are currently being used to regulate air emissions in Minnesota. As stated in the SONAR the list of HRVs is not inclusive and the absence of an HRV or MHRV for a chemical does not imply that there are no health risks associated with emissions of that chemical to air. As presented in responses to the MPCA's comments, MDH recognizes that health based values other than HRVs are suitable for use in protecting the public's health. MDH provides analyses of the suitability of external values when they become important in such processes as the MPCA's Air Toxic Reviews for facilities. Currently it is possible for health-based values produced by the U.S. EPA, California EPA, and ATSDR to be used in an air toxic review. Therefore, statements like "Minnesota children could be subjected to exposures 570 times the California limit without even triggering agency concern or regulatory rule" are incorrect.

As an additional note, the Sierra Club indicates that MDH has not proposed a HRV for 1,1,1-trichloroethane. In fact, MDH has proposed an acute HRV for methyl chloroform (1,1,1-trichloroethane).

The rules and/or SONAR should be changed to underline ongoing authority and responsibility of the health department to assess risks from toxic chemicals.

This is not a new issue and in fact has been a point of contention between MDH and the Sierra Club and has been addressed in responses #1 and #2 to the MPCA.

Responses to Comments on Proposed Permanent Rules Relating to Health Risk Values: <u>Representative Jean Wagenius</u>

1. Staff's choice to be protective only to the 1 in 100,000 lifetime cancer risk level is without rational basis and should be modified to the 1 in 1,000,000 used by many other states.

Comments addressing additional lifetime cancer risk and children's health are presented above in "**Responses to Comments on Proposed Permanent Rules Relating to Health Risk Values: General responses to the Sierra Club, the Women's Cancer Resource Center, and Representative Jean Wagenius who made similar comments regarding the HRV rule."**

2. Staff has decided to allow suspect chemicals to go unregulated contrary to statute which requires a reasonable margin of safety to adequately protect the health of infants, children and adults.

In general, the decisions made regarding development of HRVs were made based on collaboration between MDH staff and MDH's external advisory work group.

HRVs are developed using the best science available. Producing numbers where data are of poor quality or non-existent is not science – it is policy. Developing numbers using poor quality data is certainly possible, but it is a separate process than the science-based HRV development process and falls into the realm of risk management.

Uncertainty factors are used because of unknowns in the risk assessment process or the data set used to derive health-based values. Uncertainty factors have nothing to do with the safety of a chemical. A HRV for a chemical with a very low intrinsic toxicity could have a large uncertainty factor if there were few data available. Conversely, a HRV for a very toxic chemical could have a small uncertainty factor if there was a large amount of information about that chemical data available. The limitation of the size of uncertainty factors is a data quality issue.

The decision to develop HRVs for possible carcinogens on noncarcinogenic endpoints is consistent with current U.S. EPA policy. This classification of carcinogens is used for chemicals where the evidence for cancer causing ability is weak.

MDH has not developed chronic HRVs for chemicals where only sub chronic data are available. This was done to eliminate the need for the use of an additional uncertainty factor in the calculation of a HRV. There is nothing that precludes the use of the additional uncertainty factor by the agency that is applying the HRV. MDH has issued guidance in the form of a memo on this issue to the MPCA.

3. Staff's use of a 70 year life time expectancy does not adequately protect children born today.

The use of a 70 year life expectancy is a default assumption currently suggested by the U.S. EPA. There has been some discussion regarding the use of this default, but the argument usually made is that the assumption is overly protective. Most individuals move a number of times during their lifetime so there are relatively few individuals who actually spend 70 years in one place being exposed to the same group of chemicals. As

with all default assumptions used in the risk assessment process, when additional information becomes available the assumptions will be changed or they will no longer be sued as defaults. Historically, because the defaults used are conservative, most times additional information has led to less restrictive numbers.

A final note

MDH regrets the misunderstanding. The agency is in no way advocating the use of children as experimental subjects. However, data from occupational or general population exposures are often collected and analyzed. Obviously, in these instances human data are more relevant than experimental studies in animals.

Responses to Comments on Proposed Permanent Rules Relating to Health Risk Values: Hawkins, Inc. and US Filter

Both facilities provided comment regarding the appropriateness of using the IRIS database as a primary source of information for the development of MDH's HRV rule.

Comments were based on a Federal Register notice (pages 46927-46935, 2001) that stated that the U.S. EPA IRIS database was not a comprehensive toxicological database and that any state agency using IRIS should not rely exclusively on IRIS but should consider all credible and relevant information that is submitted in any particular rulemaking. This is an acknowledgement by the agency that the IRIS database is limited in that health-based values have been developed for fewer 600 chemicals of the tens of thousands of chemicals that are emitted into the atmosphere. It is also an acknowledgement that because of staff limitations some of the files contained in the database may not contain the most current information.

MDH's uses the IRIS database as a primary source of information; however, before any value (whether from IRIS or another data source) was used to develop a HRV, staff analyzed the information to determine whether its use conformed to the guidelines established by MDH's external work group. Staff also determined whether or not there was more current information available. Drafts of proposed HRVs were circulated and comments solicited. All comments and offers of additional information regarding individual HRVs were considered before the chemical was added to the rule. MDH has considered all relevant and credible information in the development of HRVs. Similar considerations will be a part of future HRV revisions.

Responses to Comments on Proposed Permanent Rules Relating to Health Risk Values: Minnesota Public Health Association

MDH thanks the Minnesota Public Health Association (MPHA) for its support regarding the proposed the proposed rule establishing HRVs.

The request made by the MPHA for periodic review and revision of HRVs was addressed in responses 1 and 2 to the MPCA.

Responses to Comments on Proposed Permanent Rules Relating to Health Risk Values: Interplastic Corporation

Interplastics comments on the rule pertained to rule part 4717.8150, item M dicyclopentadiene (DCPD).

Setting any HRV limit for DCPD is not appropriate because of the difficulties encountered with establishing reliable standards and with performing the test methods for DCPD in air. Pure DCPD is a solid at ambient temperatures, and breaks down when temperatures are elevated in analytical resting. These factors can produce unreliable results, especially at the levels proposed.

MDH acknowledges that there may be difficulties in testing for some of the proposed HRVs; however, this is an application issue. As stated in the SONAR, HRVs and MHRVs are based only on the best health effects information available and are not adjusted for such technological considerations as limits of detection or ease of removal.

If the Minnesota Department of Health proceeds with promulgating an HRV for DCPD, the limit should be based on the American Conference of Governmental Industrial Hygenists (ACGIH) limit of 5 ppm. This is also the same limit used by OSHA for a PEL standard.

As explained in the SOANR, MDH has developed HRVs to assess the risk of exposures to chemicals or mixtures of chemicals in ambient air. Ambient air is not workplace air, therefore, HRVs do not apply to workplace exposures. Workplace air is regulated by the Occupational Health and Safety Administration (OSHA). MDH does not use workplace guidelines or standards to develop health-based values for protection of the general population. The reasons for this approach are presented in the SONAR.

List of Abbreviations

ACGIH - American Conference of Governmental Industrial Hygenists
ATSDR - Agency for Toxic Substances and Disease Registry
CAS number - Chemical Abstracts Service Registry number
DCPD - Dicyclopentadiene
HEAST - (U.S. EPA Heast) – United States Environmental protection Agency's Health Effect's Assessment Summary Tables
HRVs - Health Risk Value
IRIS - (U.S. EPA IRIS database) – United States Environmental Protection Agency's Integrated Risk Information System
MDH - Minnesota Department of Health
MHRV - Multimedia health Risk Value
MPCA - Minnesota Pollution Control Agency

OSHA - Occupational Safety and Health Administration
PEL - Permissible Exposure Limit
REL - Reference Exposure Level
SONAR - Statement of Need and Reasonableness