resolution, and upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record.

It is further ordered, That Haewoo Air & Shipping Co., Ltd. d/b/a Haewoo Shipping Co., Ltd. is designated Respondent in this proceeding;

It is further ordered, That the Commission's Bureau of Enforcement is designated a party to this proceeding;

It is further ordered, That notice of this Order be published in the Federal Register, and a copy be served on parties of record;

It is further ordered, That other persons having an interest in participating in this proceeding may file petitions for leave to intervene in accordance with Rule 72 of the Commission's Rules of Practice and Procedure, 46 CFR 502.72;

It is further ordered, That all further notices, orders, and/or decisions issued by or on behalf of the Commission in this proceeding, including notice of the time and place of hearing or prehearing conference, shall be served on parties of record;

It is further ordered, That all documents submitted by any party of record in this proceeding shall be directed to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, and comply with Subpart H of the Commission's Rules of Practice and Procedure, 46 CFR 502.111–119, and shall be served on parties of record; and

It is further ordered, That in accordance with Rule 61 of the Commission's Rules of Practice and Procedure, 46 CFR 502.61, the initial decision of the Administrative Law Judge shall be issued by January 20, 1997, and the final decision of the Commission shall be issued by May 20, 1997.

By the Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 96–13056 Filed 5–22–96; 8:45 am]

BILLING CODE 6730–01–M

GENERAL ACCOUNTING OFFICE

Federal Accounting Standards Advisory Board; Meeting

AGENCY: General Accounting Office.

ACTION: Notice of Meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. No. 92–463), as amended, notice is hereby given that the Federal Accounting Standards Advisory Board will meet on Thursday, May 30, 1996, from 9 a.m. to 4 p.m. in room 7C13 of the General Accounting Office, 441 G St., NW., Washington, DC.

The purpose of the meeting is to discuss and review the (1) *Accounting for Natural Resources* document, (2) JFMIP Cost Accounting Systems and Reporting project, (3) *Invitation for Views: Accounting for the cost of Capital* document, and (4) Rule 203 of the AICPA's Code of Ethics.

Any interested person may attend the meeting as an observer. Board discussions and reviews are open to the public.

FOR FURTHER INFORMATION CONTACT: Ronald S. Young, Executive Staff Director, 750 First St., NE., Room 1001, Washington, DC. 20002, or call (202) 512–7350.

Authority: Federal Advisory Committee Act. Pub. L. No. 92–463, section 10(a)(2), 86 Stat. 770, 774 (1972) (current version at 5 U.S.C. app. section 10(a)(2) (1988); 41 CFR 101–6.1015 (1990).

Dated: May 20, 1996.

[FR Doc. 96–13040 Filed 5–22–96; 8:45 am]

BILLING CODE 1610–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA 317]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health and Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Request:* Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* State Medicaid Eligibility Quality Control Sampling Plan; *Form No.:* HCFA–317; *Use:* The State MEQC sampling plan is necessary for HCFA to monitor the States' operation of the MEQC system. The sampling plan includes all data involved in the States' sample selection process—population sizes and sample frame lists, sample sizes, sample selection procedures, and claims collection procedures; *Frequency:* Annually; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 55; *Total Annual Responses:* 110; *Total Annual Hours:* 2,640.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: May 16, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–12962 Filed 5–22–96; 8:45 am]

BILLING CODE 4120–03–P

Agency for Toxic Substances and Disease Registry

[ATSDR–110]

Minimal Risk Levels for Priority Substances and Guidance for Derivation

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (42 U.S.C. 9604 et seq.), as amended by the Superfund Amendments and Reauthorization Act (SARA) (Pub. L. 99–499), requires that

ATSDR develop jointly with the U.S. Environmental Protection Agency (EPA), in order of priority, a list of hazardous substances most commonly found at facilities on the CERCLA National Priorities List (NPL) (42 U.S.C. 9604(i)(2)); prepare toxicological profiles for each substance included on the priority list of hazardous substances, and to ascertain in the toxicological profiles, significant human exposure levels (SHELs) for hazardous substances in the environment, and the associated acute, subacute, and chronic health effects (42 U.S.C. 9604(i)(3)); and assure the initiation of a research program to fill identified data needs associated with the substances (42 U.S.C. 9604(i)(5)). The ATSDR Minimal Risk Levels (MRLs) were developed in response to the mandate for SHELs and to provide screening levels for health assessors and other responders to identify contaminants and potential health effects that may be of concern at hazardous waste sites and releases.

This notice announces the internal guidance for derivation of MRLs for priority hazardous substances by ATSDR. The guidance represents the agency's current approach to deriving MRLs and reflects the most current scientific assessment. Comments from the public on the process of deriving MRLs are welcome. The MRLs for a particular substance are published in the toxicological profile for that substance. A listing of the current published MRLs is provided at the end of the notice.

ADDRESSES: Comments on this notice should bear the docket control number ATSDR–110 and should be submitted to: Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

FOR FURTHER INFORMATION CONTACT: Dr. Selene Chou, Division of Toxicology, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mailstop E–29, Atlanta, Georgia 30333, telephone (404)639–6308 or FAX (404)639–6315.

SUPPLEMENTARY INFORMATION: CERCLA requires that ATSDR prepare toxicological profiles for priority hazardous substances, and to ascertain significant human exposure levels for these substances in the environment, and the associated acute, subacute, and chronic health effects (42 U.S.C. 9604(i)(3)). Minimal Risk Levels (MRLs) were developed as an initial response to the mandate. Following discussions with scientists within the HHS and the EPA, ATSDR chose to adopt a practice similar to that of the EPA's Reference Dose (RfD) and Reference Concentration (RfC) for deriving substance-specific levels. An MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure. These substance- specific estimates, which are intended to serve as screening levels, are used by ATSDR health assessors and other responders to identify contaminants and potential health effects that may be of concern at hazardous waste sites and releases. It is important to note that MRLs are not intended to define clean-up or action levels for ATSDR or other Agencies.

The toxicological profiles include an examination, summary, and interpretation of available toxicological information and epidemiologic evaluations of a hazardous substance. During the development of toxicological profiles, MRLs are derived when ATSDR determines that reliable and sufficient data exist to identify the target organ(s) of effect, or the most sensitive health effect(s) for a specific exposure duration for a given route of exposure to the substance. MRLs are based on noncancer health effects only and are not based on a consideration of cancer effects. Inhalation MRLs are exposure concentrations expressed in units of parts per million (ppm) for gases and volatiles, or milligrams per cubic meter (mg/m3) for particles. Oral MRLs are expressed as daily human doses in units of milligrams per kilogram per day (mg/kg/day).

ATSDR uses the no-observed-adverse-effect-level/uncertainty factor approach to derive MRLs for hazardous substances. The MRLs are set below levels that, based on current information, might cause adverse health effects in the people most sensitive to such substance-induced effects (Barnes and Dourson 1988; EPA 1990). MRLs are derived for acute (1–14 days), intermediate (15–364 days), and chronic (365 days and longer) exposure durations and for the oral and inhalation routes of exposure. Currently, MRLs for the dermal route of exposure are not derived because ATSDR has not yet identified a method suitable for this route of exposure. MRLs are generally based on the most sensitive substance-induced end point considered to be of relevance to humans. ATSDR does not use serious health effects (such as irreparable damage to the liver or kidneys, or birth defects) as a basis for establishing MRLs. Exposure to a level above the MRL does not mean that adverse health effects will occur.

MRLs are intended to serve as a screening tool to help public health professionals decide where to look more closely. They may also be viewed as a mechanism to identify those hazardous waste sites or other hazardous substance exposures that are not expected to cause adverse health effects. Most MRLs contain some degree of uncertainty because of the lack of precise toxicological information on the people who might be most sensitive (e.g., infants, elderly, and nutritionally or immunologically compromised) to the effects of hazardous substances. ATSDR uses a conservative (i.e., protective) approach to address these uncertainties, consistent with the public health principle of prevention. Although human data are preferred, MRLs often must be based on results of animal studies because relevant human studies are lacking. In the absence of evidence to the contrary, ATSDR assumes that humans are more sensitive than animals to the effects of hazardous substances, and that certain persons may be particularly sensitive. Thus, the resulting MRL may be as much as a hundredfold below levels shown to be nontoxic in laboratory animals.

Proposed MRLs undergo a rigorous review process. They are reviewed by the Health Effects/MRL Workgroup within the Division of Toxicology; an expert panel of peer reviewers; the agency wide MRL Workgroup, with participation from other federal agencies, including EPA; and are submitted for public comment through the toxicological profile public comment period. Each MRL is subject to change as new information becomes available concomitant with updating the toxicological profile of the substance. MRLs in the most recent toxicological profiles supersede previously published levels. A listing of the current published MRLs is provided at the end of this notice.

Categories Used to Derive MRLs

The following health effect end points can be used to derive MRLs:

Systemic
- Respiratory
- Cardiovascular
- Gastrointestinal
- Hematological
- Musculoskeletal
- Hepatic
- Renal
- Endocrine
- Dermal
- Ocular
- Metabolic
- Body weight change
- Other systemic effects

Immunological and Lymphoreticular
Neurological
Reproductive

Developmental

To provide a better analysis of the toxic potential of the profiled substance, the same effect can be considered under more than one system category; for example, behavioral effects in the offspring can be either neurological or developmental. However, only one system category per exposure route and duration should be chosen as the basis for deriving the MRL. If two different effects within two different systems would result in the same MRL value, the MRL should be derived from the one that is best supported by data from all exposure routes and durations.

Classification of End Points as NOAELs, Less Serious LOAELs or Serious LOAELs

MRLs are derived from no-observed-adverse-effect levels (NOAELs). In the absence of NOAELs, MRLs can be derived from less serious lowest-observed-adverse-effect levels (LOAELs). MRLs are not derived from serious LOAELs. In its 1986–1988 Biennial Report Volume II, ATSDR defines an adverse health effect as a harmful or potentially harmful change in the physiologic function, psychologic state, or organ structure that may result in an observed deleterious health outcome. Adverse health effects may be manifested in pathophysiologic changes in target organs, psychologic effects, or overt disease. This definition is interpreted to indicate that any effect that enhances the susceptibility of an organism to the deleterious effects of other chemical, physical, microbiological, or environmental influences should be considered adverse.

ATSDR acknowledges that a considerable amount of judgement is required in this process and that, in some cases, there will be insufficient data to decide whether or not an effect will lead to significant dysfunction. ATSDR generally will not derive an MRL if no adverse health effect has been reported in the published peer reviewed literature in any target organ (e.g., all free standing NOAELs) for a given duration. However, data from other durations and routes of exposure may lend support for selecting an appropriate end point to derive an MRL.

Deciding whether an end point is a NOAEL or a LOAEL depends in part upon the toxicity that occurs at other doses in the studies evaluated, and in part upon knowledge regarding the mechanism of toxicity of the substance. The distinction between less serious and serious LOAEL is intended to help the users of the toxicological profiles see at what levels of exposure ''major'' effects begin to appear, and whether the less serious effects occur at approximately the same levels as serious effects or at substantially lower levels of exposure. In general, a dose that evokes failure in a biological system and can lead to morbidity or mortality (e.g., acute respiratory distress or death) is referred to as a serious LOAEL. A more specific classification scheme is as follows.

No Adverse Effects

- Weight loss or decrease in body weight gain of less than 10%.
- Changes in organ weight of nontarget organ tissues not associated with abnormal morphologic or biochemical changes.
- Increased mortality over controls that is not statistically significant ($p > 0.05$).
- Some adaptive responses.

Less Serious Adverse Effects

- Reversible cellular alterations at the ultrastructural level (e.g., dilated endoplasmic reticulum) and at the light-microscopy level (e.g., cloudy swelling, fatty change).
- Necrosis (dependent upon location, distribution, reversibility or the degree of associated dysfunction), metaplasia, or atrophy with no apparent decrement of organ function.
- Serum chemistry changes, e.g., moderate elevations of serum aspartate aminotransferase (SGOT), serum alanine aminotransferase (SGPT).
- Weight loss or decrease in body weight gain of 10%–19%.
- Some adaptive responses.

Serious Effects

- Death
- Clinical effects of significant organ impairment (e.g., convulsions, icterus, cyanosis).
- Morphologic changes in organ tissues that potentially could result in severe dysfunction (e.g., marked necrosis of hepatocytes or renal tubules).
- Weight loss or decrease in body weight gain of 20% or greater.
- Serum chemistry changes (e.g., major elevations of SGOT, SGPT)
- Major metabolic effects (e.g., ketosis, acidosis, alkalosis).
- Cancer effects.

Additional guidance on the assessment of end-point-specific health effects is available upon request.

The Adequacy of Database for Derivation of an MRL

It is difficult to provide strict rules governing this determination. Each profiled substance presents its own unique situation. The following key points should be considered:

- Good quality human data are generally preferred over animal data.
- Only one MRL is derived per exposure period (acute, intermediate, or chronic) for each route of exposure.
- The MRL is generally based on the highest NOAEL (that does not exceed a LOAEL) or the lowest LOAEL for the most sensitive end point for that route and exposure period.
- Although not a preferred end point for MRL derivation, decreased body weight gain can be used when the decrease is greater than 10% and when the study provides some indication that weight loss is due to a systemic effect of toxicant and not reduced food and/or water intake.
- It is preferable to derive MRLs using data for each exposure duration. However, when this is not possible because of limitations of the database for a given duration, an MRL derived for one duration may sometimes be applicable to MRL(s) for other duration(s) of the same route based on consideration of the overall database.

Selection of Most Sensitive Effect

- The MRLs are based on the concept that a threshold level of exposure exists below which no noncancer health effect is likely to occur, and, therefore, an exposure level protective against the most sensitive effect would also be protective against all other effects. The most sensitive effect is the first adverse effect that occurs or is expected to occur in humans as dose increases. However, information on the mechanisms of action should be considered when assessing the significance of the effects. Where the target organ of effect is not clearly identified, an MRL is usually not derived. However, the lack of quantitative data for a particular system category does not preclude derivation of an MRL if other evidence, such as information from human case studies, toxicokinetics, and other exposure routes, indicates that this system would not be expected to be most sensitive to the substance for the exposure route and duration of concern.

Toxicokinetics data enter into consideration when comparing information across species, routes, and durations for determination of the most sensitive effect. Comparison of the metabolism of the compound exhibiting the toxic effect in animals with its metabolism in humans may affect the choice of the most sensitive end point. Toxicokinetic differences among species and for various chemical forms of the compound may help to explain an apparent inconsistency among studies.

Differences across routes of exposure can also be explained by different rates of absorption, metabolism (both detoxication and activation), and excretion.

Selection of a Representative, Quality Study for MRL Derivation

ATSDR emphasizes its preference for using data from humans whenever such data are reliable and appropriate for MRL derivation. However, human studies must be of sufficient duration and contain an adequate number of documented exposed individuals to be useful in risk assessment. In the absence of adequate human studies, animal studies are used. The author(s) of the study must provide enough information on the oral dose or inhalation exposure concentration administered to the treated animals to allow for estimation of an equivalent human oral dose or inhalation exposure. For both oral and inhalation studies, the data presented in the study should at least include the air, water, or food concentration, the duration of exposure, the frequency of exposure (i.e., per day and per week), the age of the animals, and evidence that the food and water consumption rates were not abnormal (e.g., from weight gain data) for an animal of similar age.

Background documents on general factors that ATSDR considers in evaluating the quality of a study are available upon request. Other general principles that have been accepted in practice when evaluating studies include:

- Considerations to the exposure scenario more likely to occur in environmental exposures. For example, drinking water or feeding studies are preferred over gavage oil studies for oral exposures.
- Determination whether the study data show a dose-response consistent with other studies.

The following effects are not used for MRL derivation:

- Increased incidence of mortality.
- Serious LOAELs.
- Health effects that occur in test species as a result of mechanisms, or metabolic processes that are not found in humans (e.g., α2μ-globulin nephropathy in male rats).
- Spontaneously occurring disorders that are species and gender related (e.g., chronic progressive nephropathy in male rats).
- Effects of unknown biological significance, based on mechanism of action, that do not affect known target organs.
- Cancer effects.

Computation of Inhalation MRLs

1. Extrapolating From Animals to Humans

When animal data is used in the absence of adequate quantitative human data, exposure concentrations should be converted to human equivalent concentrations by using dosimetry adjustment in accordance with EPA (1990), ''Interim Methods for Development of Inhalation Reference Doses'' (EPA/600/8–90/066A, August 1990). Standard reference values should be obtained from EPA (1988): ''Recommendations for and Documentation of Biological Values for Use in Risk Assessment'' (EPA 600–6–87/008, February, 1988).

For inhalation exposures to gases or vapors, it may be necessary to convert to human equivalent exposures for respiratory effects (e.g., using the regional gas dose ratio for the targeted region of the respiratory tract) or extra-respiratory effects (e.g., using the blood to air partition coefficient ratio).

For inhalation exposure to particles, it may also be necessary to convert to human equivalent exposures for respiratory effects (e.g., using the regional deposited dose ratio for the targeted region of the respiratory tract), or extrarespiratory effects (e.g., using the regional deposited dose ratio and uptake from the entire respiratory system).

2. Adjusting From Intermittent to Continuous Dosing

ATSDR defines an MRL as ''an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure''. The ideal study would involve continuous dosing over the course of the study. If a study did not involve continuous dosing over the entire exposure period, an adjustment is usually made. The ''intermittent exposure dose'' (either the NOAEL or LOAEL of the critical effect selected to be used for MRL derivation) is multiplied by correction factors to adjust for full day and week exposures. For example, in intermediate (longer than 14 days) or chronic (longer than 364 days) studies in which the experimental animals were dosed for 6 hours a day for 5 days a week, the estimated ''adjusted dose'' becomes:

Adjusted dose = Intermittent dose × (6 hours/24 hours) × (5 days/7 days)

Intermediate and chronic duration inhalation studies are usually dose-adjusted for day and week exposures; acute duration inhalation studies can be duration adjusted from intermittent exposures to 24 hours continuous exposure, but are not adjusted to 1 week. For example, acute studies in which animals were exposed for 6 hours/day for 3 days can be adjusted as follows:

Adjusted dose = Intermittent dose × (6 hours/24 hours)

However, making duration adjustments may not be appropriate in every instance. The toxicokinetics and mechanism of action should be examined to the fullest extent possible before a determination is made to adjust for intermittent exposures. The following are some factors to consider in adjusting for dose and duration.

- When the critical effects are mainly dependent on the exposure concentrations and the substance being tested is rapidly metabolized and/or excreted, dose adjustment is inappropriate.
- If the effects being examined are mainly duration dependent (e.g., longer periods of exposure increase the severity of the effects being studied) and metabolism/excretion is moderate to slow, or the study identifies a cumulative effect, duration adjustment may be appropriate.

3. Converting From Salt to Parent Substance

Salt concentrations or doses are converted to equivalent concentrations or doses of the parent substance by multiplying by the molecular weight ratio of parent to salt.

Computation of Oral MRLs

1. Converting From Concentration to Dose

For feeding studies, the equation for the conversion from food concentrations is:

(ppm in food) × (f/kg body weight) = mg/kg/day

The food consumption factor (f) is kg of food consumed per day. Unless the food consumption rate and body weights are available, standard reference values should be obtained from EPA (1988).

For drinking water studies, the equation for conversion from water concentrations is:

(ppm in water) × (C/kg body weight) = mg/kg/day

The water consumption rate (C) is liters of water consumed per day. Unless C and body weights are provided in the study, standard reference values should be obtained from EPA (1988) or EPA (1986), as appropriate.

2. Converting From Intermittent to Daily Dosing

By definition an MRL is ''an estimate of the daily human exposure to a hazardous substance that is likely to be without an appreciable risk of adverse noncancer health effects over a specified duration of exposure''. If the principal study did not involve daily dosing over the entire exposure period, an adjustment is usually made. The ''intermittent dose'' is multiplied by the fraction of the study days over which the test animals were actively dosed. Acute oral studies are not adjusted to 1 week; intermediate and chronic oral studies are usually dose-adjusted to full week exposures. For example, for animals orally dosed weekly 5 days a week, the estimated ''continuous dose'' becomes:

adjusted dose = intermittent dose × (5 days/7 days)

Uncertainty factors and modifying factor

When sufficient human data are not available to allow an accurate assessment of noncancer health risks, ATSDR may extrapolate from available information using uncertainty factors (UFs) to account for different areas of uncertainty in the database to derive MRLs. In addition, a modifying factor (MF) may be applied to reflect additional scientific judgement on the database.

MRLs are derived from human equivalent no-observed-adverse-effect levels and are calculated as follows:

$MRL = (NOAEL)_{HEC} / (UF \times MF)$

When an appropriate NOAEL does not exist, the lowest LOAEL should be used and a UF is applied for the use of a LOAEL. Additional uncertainty factors for human variability to protect sensitive subpopulations, for interspecies extrapolation when animal studies are used for derivation of MRLs, and for extrapolation across exposure durations are also used.

The default value for each individual UF is 10; if complete certainty in data exists, a value of one can be used; and an intermediate value is three. By multiplying these individual uncertainty factors, a combined UF is obtained.

The use of UFs and MFs should be based on scientific judgement on a case-by-case basis. General guidelines are as follows:

Intrahuman variation

An UF of 10 is generally used to account for intrahuman variation. However, a UF of 3 or 1 may be applied when a large epidemiologic study or a study of the sensitive population was used.

Interspecies Extrapolation

In the absence of adequate human data, animal data are used; a UF of 10 is generally used to account for extrapolation from animals to humans. However, a UF of 3 or 1 may also be used when comparative toxicological data indicate that similar effects are expected in humans at comparable exposure levels. For inhalation MRLs, when dosimetry adjustment is made for converting animal exposure levels to human equivalent concentrations, a UF of 3 is generally applied to account for any remaining uncertainty (Jarabek and Segal 1994).

LOAEL to NOAEL Extrapolation

MRLs are derived from NOAELs. In the absence of a NOAEL, the lowest LOAEL that causes less serious adverse health effects is used, and a UF of 10 is generally applied. When the less serious LOAEL approaches the threshold level, that is, only minimal effects are observed representing an early indication of toxicity, the effect level is considered to be a minimal LOAEL, and a UF of 3 may be used.

Extrapolation Across Durations

It is preferable to derive MRLs using data for each exposure duration. However, when the database supports extrapolation across acute, intermediate, or chronic exposure durations, a UF may be applied based on scientific judgement. For example, the chronic inhalation MRL for chlordane was derived from the intermediate inhalation MRL with an additional UF of 10 to account for across duration extrapolation; the chronic inhalation MRL was supported by the limited data on chronic exposure as well as the data on oral exposure.

Modifying Factor (MF)

An MF greater than zero and up to 10 may be applied to reflect additional concerns about the database not covered by the UFs. The default value for MF is 1. An example is the use of an MF of 3 to account for the incomplete database in deriving the chronic oral MRL for 4,4′-methylenebis(2-chloroaniline). Another possible consideration is that if a test substance is known to bioaccumulate, some studies may overestimate the dose needed to cause effects. In such cases, a modifying factor may be applied.

EPA RfDs and ATSDR MRLs

The current approach for MRL derivation by ATSDR is similar to the methods used by EPA to derive Reference Doses (RfDs) and Reference Concentrations (RfCs) for chronic exposures. The following table shows the difference in methodology used by ATSDR and EPA in deriving MRLs and RfDs/RfCs respectively.

As with RfD methodology, in deriving MRLs, ATSDR uses UFs and MFs to account for extrapolation from animals to humans, from LOAEL to NOAEL, for intraspecies variation, for across duration extrapolation, and for professional judgement on the database. In addition, EPA uses a UF for an incomplete database (EPA 1990) whereas ATSDR incorporates scientific judgement, including an incomplete database in the MF. However, ATSDR does not extrapolate across route of exposure at this time. It is recognized that the EPA derives RfDs as part of its regulatory decision-making process. Extrapolation across route of exposure (most commonly using data from inhalation studies to estimate levels by the oral route) is sometimes used to develop an RfD where there is inadequate route-specific information.

Because MRLs may be based on more recent data and are derived using a slightly different methodology, or because MRLs are derived as a result of different scientific judgement, MRLs and RfDs (or RfCs) for the same substance are not necessarily of the same value.

	MRL	RfD/RfC
Exposure duration.	Acute Intermediate Chronic	Chronic.
Route of exposure.	Oral	Oral.
	Inhalation	Inhalation.
UFs used:		
Human variability.	Yes	Yes.
Interspecies extrapolation.	Yes	Yes.
LOAEL to NOAEL.	Yes	Yes.
Extrapolation across duration.	Yes	Yes.
Incomplete database.	No	Yes.
Across route extrapolation.	No	Yes.
MF	Yes	Yes.

MRLs for Essential Trace Elements

Since many nutritionally essential elements have been found to be

common contaminants at some toxic waste sites, consideration was given to both essentiality and toxicity when deriving MRLs for these substances. Special reference was given to background levels and levels that have been published as Recommended Dietary Allowances (RDA) or Estimated Safe and Adequate Daily Dietary Intakes (ESADDIs) by the Food and Nutrition Board of the National Research Council. MRLs should not be in conflict with the corresponding RDAs and should be protective for all age groups.

MRLs vs. Ambient Levels

Since MRLs serve as screening tools for health assessors, it is important to compare MRLs with ambient levels reported in environmental monitoring studies. When MRLs are lower than ambient levels, the relevance of the MRLs is in question, and special consideration is warranted.

Future Approaches

ATSDR is considering the application of physiologically based pharmacokinetic (PBPK) modeling to enhance understanding of dose and across-route extrapolations. In addition, ATSDR is evaluating the utility of Benchmark Dose modelling, to obtain low-incidence response exposure levels calculated from mathematically fitted dose-response curves, as an adjunct to the current NOAEL/LOAEL approach in deriving MRLs.

References

Barnes DG and Dourson M (1988). Reference Dose (RfD): Description and Use in Health Risk Assessments. Regulatory Toxicology and Pharmacology 8:471–486.

EPA (1986). Research and Development: Reference Values for Risk Assessment. (ECAO–CIN–477 September 1986).

EPA (1988). Recommendations for and Documentation of Biological Values for Use in Risk Assessment. (EPA 600–6–87/008 February 1988).

EPA (1990). Interim Methods for Development of Inhalation Reference Concentrations. (EPA/600/8–90/066A August 1990).

Jarabek AM and Segal SA. (1994). Noncancer Toxicity of Inhaled Air Pollutants: Available Approaches for Risk Assessment and Risk Management. In: Patrick DR, ed. Toxic Air Pollution Handbook. New York: Van Nostrand Reinhold, pp. 529–541.

Dated: May 17, 1996.

Claire V. Broome,

Deputy Administrator, Agency for Toxic Substances and Disease Registry.

ATSDR Minimal Risk Levels (MRLs) For Hazardous Substances

[March 1996]

Substance name	CAS No.	Route	Duration	Value	Factors	End point
ACENAPHTHENE	000083–32–9	ORAL	INTERMEDIATE	0.6 mg/kg/day	300	Hepatic.
ACETONE	000067–64–1	INHALATION	ACUTE	26 ppm	9	Neurological.
		INHALATION	INTERMEDIATE	13 ppm	100	Neurological.
		INHALATION	CHRONIC	13 ppm	100	Neurological.
		ORAL	INTERMEDIATE	2 mg/kg/day	100	Hematological.
ACROLEIN	000107–02–8	INHALATION	ACUTE	0.00005 ppm	100	Ocular.
		INHALATION	INTERMEDIATE	0.000009 ppm	1000	Respiratory.
		ORAL	CHRONIC	0.0005 mg/kg/day	100	Hematological.
ACRYLONITRILE	000107–13–1	INHALATION	ACUTE	0.1 ppm	10	Neurological.
		ORAL	ACUTE	0.1 mg/kg/day	100	Developmental.
		ORAL	INTERMEDIATE	0.01 mg/kg/day	1000	Reproductive.
		ORAL	CHRONIC	0.04 mg/kg/day	100	Hematological.
ALDRIN	000309–00–2	ORAL	ACUTE	0.002 mg/kg/day	1000	Developmental.
		ORAL	CHRONIC	0.00003 mg/kg/day	1000	Hepatic.
AMMONIA	007664–41–7	INHALATION	ACUTE	0.5 ppm	100	Respiratory.
		INHALATION	CHRONIC	0.3 ppm	10	Respiratory.
		ORAL	INTERMEDIATE	0.3 mg/kg/day	100	Other.
ANTHRACENE	000120–12–7	ORAL	INTERMEDIATE	10 mg/kg/day	100	Hepatic.
ARSENIC	007440–38–2	ORAL	CHRONIC	0.003 mg/kg/day	3	Dermal.
BENZENE	000071–43–2	INHALATION	ACUTE	0.05 ppm	300	Immunological.
BIS (2-CHLORO-ETHYL) ETHER.	000111–44–4	INHALATION	INTERMEDIATE	0.02 ppm	1000	Body Weight.
BIS (CHLORO-ETHYL) ETHER.	000542–88–1	INHALATION	INTERMEDIATE	0.0003 ppm	100	Respiratory.
BORON	007440–42–8	ORAL	INTERMEDIATE	0.01 mg/kg/day	1000	Developmental.
BROMODICHLOROME-THANE.	000075–27–4	ORAL	ACUTE	0.04 mg/kg/day	1000	Hepatic.
		ORAL	CHRONIC	0.02 mg/kg/day	1000	Renal/Urinary
BROMOFORM	000075–25–2	ORAL	ACUTE	0.6 mg/kg/day	100	Nurological.
		ORAL	CHRONIC	0.2 mg/kg/day	100	Hepatic.
BROMOMETHANE	000074–83–9	INHALATION	ACUTE	0.05 ppm	100	Neurological.
		INHALATION	INTERMEDIATE	0.05 ppm	100	Neurological.
		INHALATION	CHRONIC	0.005 ppm	100	Neurological.
		ORAL	INTERMEDIATE	0.003 mg/kg/day	100	Gastrointestinal.
CADMIUM	007440–43–9	INHALATION	CHRONIC	0.0002 mg/m^3	10	Renal/Urinary.
		ORAL	CHRONIC	0.007 mg/kg/day	3	Renal/Urinary.
CARBON DISULFIDE	000075–15–0	INHALATION	CHRONIC	0.3 ppm	30	Neurolgical.
		ORAL	ACUTE	0.01 mg/kg/day	300	Hepatic.
CARBON TETRA-CHLORIDE.	000056–23–5	INHALATION	ACUTE	0.2 ppm	300	Hepatic.
		INHALATION	INTERMEDIATE	0.05 ppm	100	Hepatic.
		ORAL	ACUTE	0.02 mg/kg/day	300	Hepatic.
		ORAL	INTERMEDIATE	0.007 mg/kg/day	100	Hepatic.
CHLORDANE	000057–74–9	INHALATION	INTERMEDIATE	0.0002 mg/m^3	100	Hepatic.
		INHALATION	CHRONIC	0.00002 mg/m^3	1000	Hepatic.
		ORAL	ACUTE	0.001 mg/kg/day	1000	Developmental.

ATSDR MINIMAL RISK LEVELS (MRLS) FOR HAZARDOUS SUBSTANCES—Continued

[March 1996]

Substance name	CAS No.	Route	Duration	Value	Factors	End point
		ORAL	INTERMEDIATE	0.0006 mg/kg/day	100	Hepatic.
		ORAL	CHRONIC	0.000 mg/kg/day	100	Hepatic.
CHLORFENVINPHOS	000470–90–6	ORAL	ACUTE	0.002 mg/kg/day	1000	Neurological.
		ORAL	INTERMEDIATE	0.002 mg/kg/day	1000	Lymphoreticular.
		ORAL	CHRONIC	0.002 mg/kg/day	1000	Neurological.
CHLOROBENZENE	000108–90–7	ORAL	INTERMEDIATE	0.4 mg/kg/day	100	Hepatic.
CHLORODIBROMOMETHANE.	000124–48–1	ORAL	ACUTE	0.04 mg/kg/day	1000	Renal/Urinary.
		ORAL	CHRONIC	0.03 mg/kg/day	1000	Hepatic.
CHLOROETHANE	000075–00–3	INHALATION	ACUTE	1300 ppm	10	Neurological.
		INHALATION	INTERMEDIATE	76 ppm	100	Body Weight.
CHLOROFORM	000067–66–3	INHALATION	ACUTE	1 ppm	30	Hepatic.
		INHALATION	INTERMEDIATE	0.05 ppm	100	Hepatic.
		INHALATION	CHRONIC	0.02 ppm	100	Hepatic
		ORAL	ACUTE	0.3 mg/kg/day	100	Hepatic.
		ORAL	INTERMEDIATE	0.1 mg/kg/day	100	Hepatic.
		ORAL	CHRONIC	0.01 mg/kg/day	1000	Hepatic.
CHLOROMETHANE	000074–87–3	INHALATION	ACUTE	0.5 ppm	100	Neurological.
		INHALATION	INTERMEDIATE	0.4 ppm	100	Body Weight.
		INHALATION	CHRONIC	0.4 ppm	100	Body Weight.
CHLORPYRIFOS	002921–88–2	ORAL	ACUTE	0.003 mg/kg/day	10	Neurological.
		INHALATION	CHRONIC	0.00002 mg/m^3	10	Respiratory.
CHROMIUM, HEXAVALENT.	018540–29–9	INHALATION	INTERMEDIATE	0.00002 mg/m^3	10	Respiratory.
		INHALATION	CHRONIC	0.00002 mg/m^3	10	Respiratory.
COBALT	007440–48–4	INHALATION	INTERMEDIATE	0.00003 mg/m^3	1000	Respiratory.
CRESOL, META-	000108–39–4	ORAL	ACUTE	0.05 mg/kb/day	100	Respiratory.
CRESOL, ORTHO-	000095–48–7	ORAL	ACUTE	0.05 mg/kg/day	100	Neurological.
CRESOL, PARA-	000106–44–5	ORAL	ACUTE	0.05 mg/kg/day	100	Neurological.
CYANIDE	000057–12–5	ORAL	INTERMEDIATE	0.05 gm/kg/day	100	Reproductive.
CYCLOTETRAMETHYLENE TETRANITRAMINE.	002691–41–0	ORAL	ACUTE	0.1 mg/kg/day	1000	Neurological.
		ORAL	INTERMEDIATE	0.05 mg/kg/day	1000	Hepatic.
CYCLOTRIMETHYLENETRINITRAMINE (RDX).	000121–82–4	ORAL	ACUTE	0.06 mg/kg/day	100	Neurological.
		ORAL	INTERMEDIATE	0.03 mg/kg/day	300	Reproductive.
DDT, P,P′-	000050–29–3	ORAL	ACUTE	0.0005 mg/kg/day	1000	Developmental.
		ORAL	INTERMEDIATE	0.0005 mg/kg/day	100	Hepatic.
DI(2-ETHYLHEXYL) PHTHALATE.	000117–81–7	ORAL	ACUTE	1 mg/kg/day	100	Reproductive.
		ORAL	INTERMEDIATE	0.4 mg/kg/day	100	Developmental.
DI-N-BUTYL PHTHALATE.	000084–74–2	ORAL	INTERMEDIATE	0.6 mg/kg/day	100	Developmental .
DI-N-OCTYL PHTHALATE.	000117–84–0	ORAL	ACUTE	2 mg/kg/day	1000	Hepatic.
DIAZINON	000333–41–5	ORAL	INTERMEDIATE	0.0002 mg/kg/day	1000	Developmental.
DICHLORVOS	000062–73–7	INHALATION	ACUTE	0.002 ppm	100	Neurological.
		INHALATION	INTERMEDIATE	0.0003 ppm	100	Neurological.
		INHALATION	CHRONIC	0.00006 ppm	100	Neurological.
		ORAL	ACUTE	0.004 mg/kg/day	1000	Neurological.
		ORAL	INTERMEDIATE	0.003 mg/kg/day	10	Neurological.
DIELDRIN	000060–57–1	ORAL	ACUTE	0.00007 mg/kg/day	1000	Immunological.
		ORAL	CHRONIC	0.00005 mg/kg/day	100	Hepatic.
DIETHYL PHTHALATE	000084–66–2	ORAL	ACUTE	7 mg/kg/day	300	Reproductive.
		ORAL	INTERMEDIATE	6 mg/kg/day	300	Hepatic.
DISULFOTON	000298–04–4	INHALATION	ACUTE	0.006 mg/m^3	30	Neurological.
		INHALATION	INTERMEDIATE	2E–4 mg/m^3	30	Neurological.
		ORAL	ACUTE	0.001 mg/kg/day	100	Neurological.
		ORAL	INTERMEDIATE	9E–5 mg/kg/day	100	Developmental.
		ORAL	CHRONIC	6E–5 mg/kg/day	1000	Neurological.
ENDOSULFAN	000115–29–7	ORAL	INTERMEDIATE	0.002 mg/kg/day	100	Immunological.
		ORAL	CHRONIC	0.002 mg/kg/day	100	Hepatic.
ENDRIN	000072–20–8	ORAL	INTERMEDIATE	0.002 mg/kg/day	100	Neurological.
		ORAL	CHRONIC	0.0003 mg/kg/day	100	Neurological.
EHTYL BENZENE	000100–41–4	INHALATION	INTERMEDIATE	0.3 ppm	100	Developmental.
ETHYLENE GLYCOL	000107–21–1	ORAL	CHRONIC	2 mg/kg/day	100	Renal/Urinary.
ETHYLENE OXIDE	000075–21–8	INHALATION	INTERMEDIATE	0.09 ppm	100	Renal/Urinary.
FLUORANTHENE	000206–44–0	ORAL	INTERMEDIATE	0.4 mg/kg/day	300	Hepatic.
FLUORENE	000086–73–7	ORAL	INTERMEDIATE	0.4 mg/kg/day	300	Hepatic.

ATSDR MINIMAL RISK LEVELS (MRLS) FOR HAZARDOUS SUBSTANCES—Continued

[March 1996]

Substance name	CAS No.	Route	Duration	Value	Factors	End point
FUEL OIL NO. 2	068476–30–2	INHALATION	ACUTE	0.02 mg/m^3	1000	Neurological.
HEXACHLOROBENZENE.	000118–74–1	ORAL	ACUTE	0.008 mg/kg/day	300	Developmental.
		ORAL	INTERMEDIATE	0.0003 mg/kg/day	300	Reproductive.
		ORAL	CHRONIC	0.00002 mg/kg/day	1000	Developmental.
HEXACHLOROBUTADIENE.	000087–68–3	ORAL	INTERMEDIATE	0.0002 mg/kg/day	1000	Renal/Urinary.
HEXACHLOROCYCLOHEXANE, BETA-.	000319–85–7	ORAL	INTERMEDIATE	0.0003 mg/kg/day	300	Hepatic.
HEXACHLOROCYCLOHEXANE, GAMMA-.	000058–89–9	ORAL	ACUTE	0.01 mg/kg/day	300	Neurological.
		ORAL	INTERMEDIATE	0.00004 mg/kg/day	300	Immunological.
HEXACHLOROETHANE	000067–72–1	INHALATION	ACUTE	0.5 ppm	100	Neurological.
		INHALATION	INTERMEDIATE	0.09 ppm	100	Respiratory.
		ORAL	ACUTE	0.1 mg/kg/day	100	Hepatic.
		ORAL	INTERMEDIATE	0.01 mg/kg/day	100	Hepatic.
HYDRAZINE	000302–01–2	INHALATION	INTERMEDIATE	0.0002 ppm	1000	Hepatic.
ISOPHORONE	000078–59–1	ORAL	INTERMEDIATE	3 mg/kg/day	100	Other.
		ORAL	CHRONIC	0.2 mg/kg/day	1000	Hepatic.
JP–4 JET FUEL	050815–00–4	INHALATION	INTERMEDIATE	9 mg/m^3	300	Hepatic.
JP–7 JET FUEL	HZ0600–22–T	INHALATION	CHRONIC	0.3 mg/m^3	300	Hepatic.
KEPONE	000143–50–0	ORAL	ACUTE	0.01 mg/kg/day	100	Neurological.
		ORAL	INTERMEDIATE	0.0005 mg/kg/day	100	Renal/Urinary.
		ORAL	CHRONIC	0.0005 mg/kg/day	100	Renal/Urinary.
KEROSENE	008008–20–6	INHALATION	INTERMEDIATE	0.01 mg/m^3	1000	Hepatic.
M–XYLENE	000108–38–3	ORAL	INTERMEDIATE	0.6 mg/kg/day	1000	Hepatic.
MANGANESE	007439–96–5	INHALATION	CHRONIC	0.0003 mg/m^3	100	Neurological.
MERCURY, INORGANIC	HZ0900–19–T	ORAL	ACUTE	0.007 mg/kg/day	100	Renal/Urinary.
		ORAL	INTERMEDIATE	0.002 mg/kg/day	100	Renal/Urinary.
MERCURY, METALLIC	007439–97–6	INHALATION	ACUTE	0.00002 mg/m^3	100	Developmental.
		INHALATION	CHRONIC	0.000014 mg/m^3	100	Neurological.
METHOXYCHLOR	000072–43–5	ORAL	ACUTE	0.02 mg/kg/day	1000	Reproductive.
		ORAL	INTERMEDIATE	0.02 mg/kg/day	1000	Reproductive.
METHYL PARATHION	000298–00–0	ORAL	CHRONIC	0.0003 mg/kg/day	100	Neurological.
METHYL-T-BUTYL ETHER.	001634–04–4	INHALATION	ACUTE	2 ppm	100	Neuorlogical.
		INHALATION	INTERMEDIATE	0.7 ppm	100	Neurological.
		INHALATION	CHRONIC	0.7 ppm	100	Renal/Urinary.
		ORAL	ACUTE	0.4 mg/kg/day	100	Neurological.
		ORAL	INTERMEDIATE	0.3 mg/kg/day	300	Hepatic.
METHYLENE CHLORIDE.	000075–09–2	INHALATION	ACUTE	0.4 ppm	100	Neurological.
		INHALATION	INTERMEDIATE	0.03 ppm	1000	Hepatic.
		ORAL	CHRONIC	0.06 mg/kg/day	100	Hepatic.
METHYLMERCURIC CHLORIDE.	000115–09–3	ORAL	ACUTE	0.00012 mg/kg/day	10	Developmental.
		ORAL	INTERMEDIATE	0.00012 mg/kg/day	10	Developmental.
MIREX	002385–85–5	ORAL	CHRONIC	0.0008 mg/kg/day	100	Hepatic.
N-NITROSODI-N-PROPYLAMINE.	000621–64–7	ORAL	ACUTE	0.095 mg/kg/day	100	Hepatic.
NAPHTHALENE	000091–20–3	INHALATION	CHRONIC	0.002 ppm	1000	Neurological.
		ORAL	ACUTE	0.05 mg/kg/day	1000	Neurological.
		ORAL	INTERMEDIATE	0.02 mg/kg/day	300	Hepatic.
NICKEL	007440–02–0	INHALATION	INTERMEDIATE	0.00004 mg/m^3	100	Respiratory
P-XYLENE	000106–64–3	ORAL	ACUTE	1 mg/kg/day	100	Neurological.
PENTACHLOROPHENOL.	000087–86–5	ORAL	ACUTE	0.005 mg/kg/day	1000	Developmental.
		ORAL	INTERMEDIATE	0.001 mg/kg/day	1000	Hepatic.
PHENOL	000108–95–2	ORAL	ACUTE	0.6 mg/kg/day	100	Developmental.
POLYBROMINATED BIPHENYLS.	067774–32–7	ORAL	ACUTE	0.01 mg/kg/day	100	Endocrine.
POLYCHLORINATED BIPHENYLS.	001336–36–3	ORAL	CHRONIC	0.00002 mg/kg/day	300	Immunological.
PROPYLENE GLYCOL DINITRATE.	006423–43–4	INHALATION	ACUTE	0.003 ppm	10	Neurological.
		INHALATION	INTERMEDIATE	0.00004 ppm	1000	Hematological.
		INHALATION	CHRONIC	0.00004 ppm	1000	Hematological.
SELENIUM	007782–49–2	ORAL	CHRONIC	0.002 mg/kg/day	10	Dermal.
SODIUM FLUORIDE	007681–49–4	ORAL	CHRONIC	0.05 mg/kg/day	10	Musculoskeletal.
STYRENE	000100–42–5	INHALATION	CHRONIC	0.06 ppm	100	Neurological.
		ORAL	INTERMEDIATE	0.2 mg/kg/day	1000	Hepatic.

ATSDR MINIMAL RISK LEVELS (MRLS) FOR HAZARDOUS SUBSTANCES—Continued

[March 1996]

Substance name	CAS No.	Route	Duration	Value	Factors	End point
TETRACHLOROETHYLENE TETRACHLOROETHYLENE.	000127–18–4	INHALATION	ACUTE	0.2 ppm	10	Neurological.
		INHALATION	CHRONIC	0.04 PPM	100	Neurological.
		ORAL	ACUTE	0.5 mg/kg/day	1000	Development.
TITANIUM TETRACHLORIDE.	007550–45–0	INHALATION	CHRONIC	0.001 mg/m^3	90	Respiratory.
TOLUENE	0001108–88–3	INHALATION	ACUTE	3 ppm	30	Neurological.
		INHALATION	CHRONIC	1 ppm	30	Neurological.
		ORAL	ACUTE	0.8 mg/kg/day	300	Neurological.
		ORAL	INTERMEDIATE	0.02 mg/kg/day	300	Neurological.
TOTAL XYLENES	001330–20–7	INHALATION	ACUTE	1 ppm	100	Neurological.
		INHALATION	INTERMEDIATE	0.7 ppm	300	Development.
		INHALATION	CHRONIC	0.1 ppm	100	Neurological.
		ORAL	INTERMEDIATE	0.2 mg/kg/day	1000	Renal/Urinary.
TOXAPHENE	008001–35–2	ORAL	ACUTE	0.005 mg/kg/day	1000	Hepatic.
		ORAL	INTERMEDIATE	0.001 mg/kg/day	100	Hepatic.
TRICHLOROETHYLENE	000079–01–6	INHALATION	ACUTE	2 ppm	30	Neurological.
		INHALATION	INTERMEDIATE	0.1 ppm	300	Neurological.
		ORAL	ACUTE	0.5 mg/kg/day	100	Development.
		ORAL	INTERMEDIATE	0.002 mg/kg/day	100	Development.
VANADIUM	007440–62–2	INHALATION	ACUTE	0.0002 mg/m^3	100	Respiratory.
		ORAL	INTERMEDIATE	0.003 mg/kg/day	100	Renal/Urinary.
VINYL ACETATE	000108–05–4	INHALATION	INTERMEDIATE	0.01 ppm	100	Respiratory.
VINYL, CHLORIDE	000075–01–4	INHALATION	ACUTE	0.5ppm	100	Development.
		INHALATION	INTERMEDIATE	0.03 ppm	300	Hepatic.
		ORAL	CHRONIC	0.00002 mg/kg/day	1000	Hepatic.
ZINC	007440–66–6	ORAL	INTERMEDIATE	0.3 mg/kg/day	3	Hematological.
		ORAL	CHRONIC	0.3 mg/kg/day	3	Hematological.
1,1,1-TRICHLOROETHANE.	000071–55–6	INHALATION	ACUTE	2 ppm	100	Neurological.
		INHALATION	INTERMEDIATE	0.7 ppm	100	Neurological.
1,1,2,2-TETRACHLORO-ETHANE.	000079–34–5	INHALATION	ACUTE	1 ppm	10	Neurological.
		INHALATION	INTERMEDIATE	0.4 ppm	300	Hepatic.
		ORAL	ACUTE	0.3 mg/kg/day	100	Hepatic.
		ORAL	INTERMEDIATE	0.3 mg/kg/day	300	Body Weight.
		ORAL	CHRONIC	0.3 mg/kg/day	300	Body Weight.
1,1,2-TRI-CHLORO-ETHANE.	000079–00–5	ORAL	ACUTE	0.3 mg/kg/day	100	Neurological.
		ORAL	INTERMEDIATE	0.04 mg/kg/day	100	Hepatic.
1,1-DI-CHLORO-ETHENE.	000075–35–4	INHALATION	INTERMEDIATE	0.02 ppm	100	Hepatic.
		ORAL	CHRONIC	0.009 mg/kg/day	1000	Hepatic.
1,1-DI-METHYL-HYDRAZINE.	000057–14–7	INHALATION	INTERMEDIATE	0.000009 ppm	1000	Hepatic.
		INHALATION	CHRONIC	0.000009 ppm	1000	Hepatic.
1,2,3-TRI-CHLORO-PROPANE.	000096–18–4	INHALATION	ACUTE	0.0003 ppm	100	Respiratory.
		ORAL	INTERMEDIATE	0.06 mg/kg/day	100	Hepatic.
1,2-DI-BROMO-3-CHLORO-PRO-PANE.	000096–12–8	INHALATION	INTERMEDIATE	0.0002 ppm	100	Reproductive.
		ORAL	INTERMEDIATE	0.002 mg/kg/day	1000	Reproductive.
1,2-DI-CHLORO-ETHANE.	000107–06–2	INHALATION	ACUTE	0.2 ppm	100	Immunological.
		INHALATION	CHRONIC	0.2 ppm	300	Hepatic.
		ORAL	INTERMEDIATE	0.2 mg/kg/day	300	Renal/Urinary.
1,2-DI-CHLORO-ETHENE, CIS-.	000156–59–2	ORAL	ACUTE	1 mg/kg/day	100	Hematological.
		ORAL	INTERMEDIATE	0.3 mg/kg/day	100	Hematological.
1,2-DI-CHLORO-ETHENE, TRANS-.	000156–60–5	INHALATION	ACUTE	0.2 ppm	1000	Hepatic.
		INHALATION	INTERMEDIATE	0.2 ppm	1000	Hepatic.
		ORAL	INTERMEDIATE	0.2 mg/kg/day	100	Hepatic.
1,2-DI-CHLORO-PROPANE.	000078–87–5	INHALATION	ACUTE	0.05 ppm	1000	Respiratory.
		INHALATION	INTERMEDIATE	0.007 ppm	1000	Respiratory.
		ORAL	ACUTE	0.1 mg/kg/day	1000	Neurological.
		ORAL	INTERMEDIATE	0.07 mg/kg/day	1000	Hematological.
		ORAL	CHRONIC	0.09 mg/kg/day	1000	Hepatic.
1,2-DI-METHYL-HYDRAZINE.	000540–73–8	ORAL	INTERMEDIATE	0.0008 mg/kg/day	1000	Hepatic.

ATSDR MINIMAL RISK LEVELS (MRLS) FOR HAZARDOUS SUBSTANCES—Continued

[March 1996]

Substance name	CAS No.	Route	Duration	Value	Factors	End point
1,3-DI-CHLORO-PROPENE.	000542–75–6	INHALATION	INTERMEDIATE	0.003 ppm	100	Respiratory.
		INHALATION	CHRONIC	0.002 ppm	100	Respiratory.
1,3-DI-NITRO-BENZENE	000099–65–0	ORAL	ACUTE	0.008 mg/kg/day	100	Reproductive.
		ORAL	INTERMEDIATE	0.0005 mg/kg/day	1000	Hematological.
1,4-DI-CHLORO-BEN-ZENE.	000106–46–7	INHALATION	INTERMEDIATE	0.2 ppm	100	Hepatic.
		ORAL	INTERMEDIATE	0.1 mg/kg/day	100	Hepatic.
1-METHYLNAPHTHA-LENE.	000090–12–0	ORAL	CHRONIC	0.07 mg/kg/day	1000	Respiratory.
2,3,4,7,8-PENTA-CHLORO-DI-BENZO-FURAN.	057117–31–4	ORAL	ACUTE	0.000001 mg/kg/day	3000	Immunological.
		ORAL	INTERMEDIATE	0.00000003 mg/kg/day.	3000	Hepatic.
2,3,7,8-TETR-ACHLORO-DIBENZO-P-DIOXIN.	001746–01–6	ORAL	ACUTE	0.0000001 mg/kg/day	1000	Hepatic.
		ORAL	INTERMEDIATE	0.000000001 mg/kg/day.	1000	Reproductive.
		ORAL	CHRONIC	0.000000001 mg/kg/day.	1000	Reproductive.
2,4,6-TRI-CHLORO-PHENOL.	000088–06–2	ORAL	INTERMEDIATE	0.04 mg/kg/day	100	Reproductive.
2,4,6-TRI-NITROTOL-UENE.	000118–96–7	ORAL	INTERMEDIATE	0.0005 mg/kg/day	1000	Hepatic.
2,4-DI-NITRO-PHENOL	000051–28–5	ORAL	ACUTE	0.01 mg/kg/day	100	Body Weight.
2,4-DI-NITRO-TOLUENE	000121–14–2	ORAL	ACUTE	0.06 mg/kg/day	1000	Hematological.
		ORAL	INTERMEDIATE	0.05 mg/kg/day	100	Reproductive.
		ORAL	CHRONIC	0.002 mg/kg/day	100	Hematological.
2,6-DI-NITRO-TOLUENE	000606–20–2	ORAL	INTERMEDIATE	0.04 mg/kg/day	100	Neurological.
4,4°-METHYL-ENE-BIS (2-CHLOROANILINE).	000101–14–4	ORAL	CHRONIC	0.003 mg/kg/day	3000	Hepatic.
4,6-DI-NITRO-O-CRE-SOL.	000534–52–1	ORAL	ACUTE	0.004 mg/kg/day	100	Neurological.
		ORAL	INTERMEDIATE	0.004 mg/kg/day	100	Neurological.

[FR Doc. 96–12991 Filed 5–22–96; 8:45 am]

BILLING CODE 4163–70–P

Food and Drug Administration

Advisory Committee; Science Board to the Food and Drug Administration; Formation of a Subcommittee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the formation of a subcommittee of the Science Board to the Food and Drug Administration (Science Board). This subcommittee has been established to address issues related to science and research in FDA. The subcommittee's preliminary recommendations will be presented to the FDA Science Board for full public discussion at a future Science Board meeting.

FOR FURTHER INFORMATION CONTACT: Susan A. Homire, Office of Science (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) is announcing the formation of a subcommittee to the Science Board to the Food and Drug Administration. This subcommittee has been established to address issues related to science and research in FDA. The subcommittee will meet several times over the next 6 to 9 months to develop preliminary recommendations for the Science Board on a process for review of research programs within FDA. During this period there will be opportunities for public comment; these opportunities will be announced in the Federal Register at least 15 days prior to each scheduled public meeting. The subcommittee's preliminary recommendations will be presented to the Science Board for full public discussion at a future Science Board meeting. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463 (5 U.S.C. app. 2)).

Dated: May 16, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–12877 Filed 5–22–96; 8:45 am]

BILLING CODE 4160–01–F

Investigational Biological Product Trials; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting of the clinical hold review committee, which reviews the clinical hold orders that the Center for Biologics Evaluation and Research (CBER) has placed on certain investigational biological product trials. FDA is inviting any interested biological product company to use this confidential mechanism to submit to the committee for its review the name and number of