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WASHINGTON, D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

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September 26, 1994

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Subject: Advisory on the Development of a National Wildlife Criteria Program

Dear Ms. Browner:

On April 27-28, 1994, the Wildlife Criteria Subcommittee of the Ecological Processes and Effects Committee (EPEC) of the Science Advisory Board (SAB) met in Washington, D.C. to hear briefings and engage in a consultation with Agency representatives on plans for the development of a national methodology for developing wildlife criteria. Although SAB consultations typically last only a few hours and do not result in a formal report, at the request of Agency staff from the Office of Water, we spent nearly seven hours in briefings and discussion with Agency staff on this topic. Our sense from Agency staff was that a proposed national methodology was unlikely to come to the SAB for another year or so. Therefore, based on these discussions and our review of the background materials provided to the Subcommittee, we would like to provide you with our assessment of the overall program and the approaches being considered for developing wildlife criteria.

We congratulate the Agency managers and researchers for assembling thoughtful and concise background materials to facilitate our discussions. The presenters were enthusiastic about the topic of wildlife criteria, prepared insightful questions to guide our consultation, and assembled a well-organized set of briefing materials. Clearly, a main strength of the wildlife criteria development effort is the multidisciplinary nature of the Agency staff and contractors involved. In large part, the future success of the program will relate to how well the group maintains communication as the chemical, physical and biological elements necessary to develop relevant criteria are assembled.

Prior to the consultation in April, the Subcommittee was provided with a set of 34 specific questions (enclosed) regarding the development of wildlife criteria. Although we have not attempted to answer each of these, our comments are grouped in seven major categories which summarize the questions posed.

1. ECOLOGICAL RISK ASSESSMENT AND THE DEVELOPMENT OF WILDLIFE CRITERIA

> Recommendation: **The wildlife criteria program should be guided by the Agency's Ecorisk Assessment Framework, which provides a paradigm for considering integrated risks to wildlife populations from both chemical and non-chemical stressors and multiple routes of exposure. In particular, questions arising from the problem formulation phase of ecorisk assessment should be addressed.**

In 1992, several committees of the SAB reviewed technical documents supporting the Great Lakes Water Quality Initiative (GLWQI), including those portions which related to wildlife criteria for the Great Lakes. A number of the recommendations in the final report (EPA-SAB-EPEC/DWC-93-005) are relevant to the national wildlife criteria program (e.g., the relationship of wildlife criteria to ecological risk assessment, protection of populations vs. individuals, and the need to consider additional wildlife species) and are reiterated by the current Subcommittee in this letter.

The SAB report on the GLWQI recommended that wildlife criteria based on aquatic routes of exposure should be considered in the broader context of ecological risk assessment. In other words, the GLWQI, which focuses on point sources of pollution, should be related to an ecosystem management approach which incorporates multiple pathways of exposure and additional endpoints of effects for wildlife.

- We recognize that the Agency staff associated with the wildlife criteria program are operationally familiar with the Agency's landmark document, *Framework for Ecological Risk Assessment* (EPA/630/R-92/001), commonly referred to as the Ecorisk Framework. Although Agency staff made reference to evolving linkages between the Ecorisk Framework and the national wildlife criteria effort, we urge that the Framework be used more directly.

The Ecorisk Framework provides the essential and most relevant outline for development of science-based wildlife criteria. The current phase of the national wildlife criteria program is directly analogous to the initial problem formulation phase of ecorisk assessment. Careful initial scoping of relevant issues and

questions, through a thorough review of available toxicological field data for wildlife populations, will focus subsequent assessments of exposure and effects by clarifying issues of uncertainty, prioritizing long-term research needs, and providing the framework for integration of laboratory and field data. Such an exercise will also address external criticism of the need for wildlife criteria.

The Agency's guidance for developing wildlife criteria should discuss the relative risk of chemical and non-chemical stresses on wildlife populations. In keeping with the tenets of the problem formulation phase of the Ecorisk Framework, the Agency needs to clearly indicate where and when wildlife populations remain at risk when existing criteria for aquatic life are met. A critical review of real-world case studies should be conducted in the future to identify examples where wildlife populations are at incremental risk. Considering wildlife criteria in the context of ecorisk assessment automatically provides a framework for considering that chemical stressors are but one stress imposed on wildlife populations. Additional stressors may include habitat loss/fragmentation, introduction of exotic species, and various biological and physical stressors. In cases where these non-chemical stressors are more significant than chemical stressors, wildlife criteria values based on chemical stressors may be insufficient to protect wildlife populations.

Preliminary knowledge of the properties of the perturbation or chemical of concern can be used to decide which endpoints are likely to be most relevant (e.g., hydrophobic, tightly-sorbed, non-persistent chemicals are not likely to be significant for exposure via aquatic prey species and non-bioaccumulative compounds are unlikely to impact higher trophic levels).

In addition, chemical stressors for wildlife may have multi-media routes of exposure (e.g., soil and atmospheric routes, as well as water). For example, researchers have found PCB/DDT/DDE loadings in the forest soil at Hubbard Brook Experimental Forest in New Hampshire to be higher than sediment and water-column loadings to Long Island Sound[1]. In areas with important non-water exposure of wildlife to toxic chemicals, exclusive examination of water-based wildlife screening could seriously underestimate wildlife population risks.

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[1]Smith, W.H., R.C. Hale, J. Greaves, and R.J. Huggett. 1993. Trace Organochlorine Contamination of the Forest Floor of the White Mountain National Forest, New Hampshire. Environmental Science and Technology, vol. 27, pp. 2244-2246.

2. ALTERNATE APPROACHES AND METHODS FOR DERIVING WILDLIFE CRITERIA

> Recommendation: **Both approaches proposed by the Agency for deriving wildlife criteria, 1) an adaptation of the human health non-cancer approach proposed in the GLWQI and 2) a modification of the aquatic life criteria approach, are in the early stages of development, but each holds promise and should be pursued further.**

The primary approach presented to the Subcommittee is based largely on the proposed GLWQI and is an adaptation of the human health non-cancer approach with an uncertainty factor to account for interspecies variability. The majority of our comments relate to that approach, which, while clearly in the early stages of development, promises to be an innovative and valuable new method for understanding the fate and effects of contaminants in the environment. An alternate method based on modification of the aquatic life criteria approach was also presented to the Subcommittee and appeared worthy of further research. At this early stage in methodology development, we encourage the Agency to continue pursuing both options.

While the research staff involved in the wildlife criteria program are aware of the regulatory framework into which this approach must ultimately be coordinated, we think it is important to explicitly state how this developmental effort will evolve into the determination of criteria and enforceable standards. For example, the Agency should decide up-front on the level of uncertainty (i.e., variability in the data sets and level of statistical confidence) which is acceptable for specific uses of the methodology. This information in turn will help define data requirements and research needs.

Another option discussed at the meeting involved the use of egg-injection studies to assess the effects of chemicals on the avian embryo. In most cases, embryonic development represents the most sensitive stage in reproduction. However, extreme care must be taken in interpreting data on embryo toxicity derived from such studies. Egg-injection studies ignore many important physiological and behavioral factors which affect exposure (e.g., fertility and nesting behavior). In addition, the female may incorporate the chemical of concern into the egg in a different manner from that used in the egg-injection study. For example, fat-soluble chemicals are deposited into the yolk portion of the egg which has a metabolic regime different from that of the albumen. In short, experimental results may not accurately reflect reponses that would occur in nature. Other sources of experimental error include excess mortality in the embryos due to poor injection technique and adverse effects caused by the vehicle

employed as a carrier. In summary, we do not recommend the use of these studies since more valid data on effects can usually be obtained by using natural transfer of the chemical of concern from the female to the embryo and using residue analysis to quantify exposure.

3. NATIONAL VS. REGIONAL WILDLIFE CRITERIA

> Recommendation: **The objective of the Agency's wildlife criteria program should be to develop a national methodology which can in turn be used to derive regional or site-specific wildlife criteria.**

Development of national criteria per se would not be defensible given the many factors affecting regional and local wildlife populations. For example, feeding ecology and behavior of a particular species can vary markedly in different geographic locations and may exceed interspecies variability in some instances. The natural history work included in the Agency's proposed long-term research strategy will be important to define appropriate geographic areas for given wildlife criteria. This effort should be coordinated with the activities of the National Biological Survey. In addition, although one tends to think of regional or geographically-based criteria, protection of some species requires consideration of migratory patterns and home ranges. This may result in a need for criteria specific to species groups in some circumstances.

4. MODEL VALIDATION

> Recommendation: **The Agency should consider the use of hind-cast testing or case studies using existing data for well-studied chemicals of interest to validate the models and methodologies and to focus future research needs.**

Many of the proposed models and algorithms for developing wildlife criteria, and indeed the entire approach, can be fully evaluated using existing toxicology data. An initial focus on data-rich scenarios (e.g., the well-studied effects of DDT/DDE on eagle reproduction and the effects of selenium on waterfowl reproduction) would allow the theoretical basis of the model to be evaluated, as well as its applicability to real-world events. Also, this use of case studies should help focus future research needs for the development of wildlife criteria. As noted by Agency researchers, however, data cannot always be used directly from peer-reviewed literature, but instead must be reviewed for quality assurance and quality control. Many published toxicological studies do not fully confirm or measure dose to the organism, relying instead on unconfirmed estimates of exposure. We recommend direct consultation with authors of published studies when possible to double-check accuracy of data prior to its use by the Agency.

5. CHARACTERIZATION OF TOXIC EFFECTS

Recommendation: **The focus of the wildlife criteria program should remain on the protection of wildlife populations (as opposed to individuals) from the direct effects of stressors, although consideration of indirect effects should be added in the future. Methods to refine both the benchmark dose and calculated NOAEL should proceed. Wildlife criteria approaches should consider both chemical and biological transformations of chemicals when characterizing toxic effects.**

The Subcommittee strongly endorses the focus on population rather than individual organism effects, except in special cases such as endangered species. This emphasis was also recommended in the previous SAB review of the GLWQI (EPA-SAB-EPEC/DWC-93-005). We recognize, however, that due to the difficulty of measuring wildlife population effects, it is sometimes necessary to measure effects on individuals and extrapolate to population-level effects.

One method of protecting wildlife populations within the human non-cancer risk assessment paradigm is to use toxicological endpoints which can be related to population effects. Of the potential endpoints under consideration by the Agency, reproductive endpoints (e.g., number of viable young per female) are clearly the most relevant and most readily related to population effects and are therefore the clear first choice when data are available or are being generated. Mortality, while also a useful endpoint, is not always related to the response of a population to a stress. Growth and development endpoints are even harder to relate to population effects, and published data are often not comparable due to differences in experimental design. Growth and development endpoints, therefore, are not recommended for use when other alternatives exist.

Given the early stage of wildlife criteria development, we agree with the Agency's initial emphasis on direct effects of chemicals on wildlife versus indirect effects. Due to the better data sets available on direct vs. indirect effects, this focus should improve the chances for success in initial model development. However, indirect effects of chemicals on wildlife (e.g., via impacts on habitat) are extremely important and should be considered in the context of the ecorisk assessment paradigm as model development becomes more sophisticated.

With regard to the use of no observed adverse effect level (NOAEL) or lowest observed adverse effect level (LOAEL) values to establish criteria, the SAB previously recommended that the Agency develop guidance for the selection of NOAELs appropriate for protection of wildlife populations as distinct from the protection of individuals and cautioned that uncertainty factors relating LOAEL to

NOAEL are highly dependent on the dosage-spacing used in the chronic toxicity studies (EPA-SAB-EPEC/DWC-93-005). In other words, NOAEL values are sometimes extrapolated from effects data, rather than being based on direct observations. LOAEL or benchmark dose values, if based on actual measured effects, represent an adverse effect level, but provide a value with minimal uncertainty. Since no clear preference for a benchmark dose vs. a calculated NOAEL currently exists among human and ecological toxicologists, methods to refine both approaches should proceed.

The methodologies presented by the Agency (the human health non-cancer algorithm and the aquatic life criteria-derived method) use effects terms which characterize the animal's response to a chemical insult. Missing from both methods is an explicit factor acknowledging chemical and biological transformations of the chemical that may occur between the time the chemical enters the environment and the time the organism is exposed. Such transformations may substantially alter the severity and nature of the effect and/or the bioavailability of the compound. Selenium and mercury are cases in point: in aquatic environments, both are naturally transformed from inorganic to organic forms which are far more toxic. We recommend that these potential pathways be recognized explicitly within the effects and exposure terms for both methodologies; when the approach is broadened to include non-bioaccumulating chemicals, the bioaccumulation factor (BAF) term will not serve this purpose. Other transformations which should be included in the physiologically-based toxicokinetic (PB/TK) models, are those occurring within the animal that produce metabolites whose effects may differ from those of the parent compound. In the 1992 review of the GLWQI, the SAB referred to the need to consider chemical speciation, bioavailability, and persistence in the environment when establishing criteria; these considerations remain valid in the development of a national wildlife criteria methodology.

The uncertainty factors included in the exposure term represent at least two qualitatively different types of uncertainty. One type, exemplified by the interspecies uncertainty factor, will be relevant to any methodology and therefore deserves considerable attention. The current attempts to establish a range of uncertainty and guidance for deriving an uncertainty factor for specific chemicals should be considerably refined and augmented. Another type, exemplified by the LOAEL to NOAEL uncertainty factor, is necessary only where there is a paucity of relevant data. In this case, a large uncertainty factor probably renders the resulting criterion indefensible, and suggests that the Agency is better served improving the data set rather than expending substantial resources bounding the uncertainty factor.

Allometric relationships can provide useful ways to analyze data but should not be the sole basis for selection of an interspecies uncertainty factor. Many examples can be proffered that render such an approach invalid. For example, animals with similar body weight can exhibit very different sensitivities to a chemical, as seen in the case of hamsters, which are very resistant to dioxin, and guinea pigs, which are very sensitive to dioxin. We recommend that the Agency collect toxicological data on a greater number of wildlife species to improve the ecological relevance of an interspecies uncertainty factor.

6. CHARACTERIZATION OF WILDLIFE EXPOSURE

> Recommendation: **While we agree with the initial focus on persistent, bioaccumulative, organic contaminants, we recommend that the wildlife criteria methodology be developed and tested for other chemical groups, in other ecosystems and regions than the Great Lakes, and for additional wildlife species.**

During the initial stages of wildlife exposure characterization, it is imperative that expert opinion and professional judgement be used to determine, to the extent practical, what exposure will dominate, which species are likely to be maximally exposed, and which endpoints will be most ecologically meaningful at the population level. As mentioned previously, chemical, physical, and biological transformations which may alter either the fate of the compound or its biological effects must also be considered. We note that the Agency is focusing its initial wildlife criteria efforts on persistent organic contaminants that are bioaccumulated by wildlife primarily through trophic transfer through aquatic systems. While this is an appropriate place to begin, the wildlife criteria methodology should be developed and tested on other chemical groups as well, since exposure pathways, chemical forms, and primary impacted species may differ with other categories of contaminants. The methodology should also be tested in ecosystems and regions other than the Great Lakes. Specifically, trace element exposure in a western ecosystem might be used to test the robustness of the models on a qualitatively different system.

The wildlife criteria program is currently focusing exclusively on avian and mammalian species due to the lack of toxicological data for reptiles and amphibians. We agree that development of wildlife criteria at this time should focus on species which have substantial databases and upon which considerable toxicological understanding already is available. However, as stated in the SAB report on the GLWQI, the Agency should consider incorporating reptiles and amphibians into the program in the future so that wildlife criteria derived with the national methodology will adequately protect these species. The importance of

developing empirical databases for these species should be recognized in the Agency's long-term research agenda.

7. LONG-TERM RESEARCH NEEDS

> Recommendation: **In addition to continuing Agency research in the identified high-priority areas, the Agency should take greater advantage of wildlife toxicology expertise in professional societies and at other federal agencies.**

The Subcommittee strongly endorses the Agency's four proposed research areas to support development of science-based water quality criteria to protect wildlife:

a) Integrated Wildlife Population and Toxicology Research
b) Species and Exposure Extrapolation Research
c) Watershed Characterization and Diagnosis Research
d) Natural History Surveys

These research areas are consistent with recommendations made at a recent conference and book sponsored by the Society of Environmental Toxicology and Chemistry (SETAC) on the need to integrate wildlife population and toxicology research[2]. As noted previously, we urge that model development and wildlife criteria promulgation be consistent with the Agency's ecorisk assessment paradigm.

In order to define the need for additional research on toxicological endpoints and on the relevance of test species to target wildlife species, we urge the Agency to establish criteria for judging a priori the level of variability in the data sets which is acceptable for various policy and regulatory applications of the wildlife criteria methodology. As mentioned, we also recommend research on additional types of chemicals and ecosystems other than Great Lakes, as well as research to develop toxicological data on amphibians and reptiles.

Finally, since wildlife biology/toxicology expertise within the Agency is limited, we encourage the Agency to take greater advantage of the professional expertise that is available outside the Agency. In particular, professional societies can work in partnership with the Agency to define critical scientific issues, develop research needs and strategies, plan and prioritize research goals, and provide

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[2]Kendall, R.J. and T.E. Lacher, Jr., Editors. 1994. Wildlife Toxicology and Population Modeling: Integrated Studies of Agroecosystems. CRC Press/Lewis Publishing, Boca Raton, Florida. 579 pp.

external peer review. These services are often available at nominal or no cost to the Agency. Relevant professional societies include SETAC (ecotoxicology), Society for Toxicology (toxicology), American Society for Microbiology (biogeochemistry, biotransformation), and the American Chemical Society (analysis, chemical reactions).

Additionally, we encourage EPA scientists and managers to coordinate their programs with scientists in other federal agencies; science relevant to the development of wildlife criteria is also taking place at the U.S. Fish and Wildlife Service, NOAA, Department of Defense, Department of Energy, U.S. Forest Service, National Institute of Environmental Health Science, and U.S. Department of Agriculture.

We appreciate the opportunity to hear about the Agency's progress in developing a national methodology for deriving wildlife criteria, and we hope our comments will assist the Agency in that effort. We look forward to your response on the issues raised and to further review of the Agency's national methodology for wildlife criteria as it develops.

Sincerely,

Genevieve M. Matanoski

Dr. Genevieve M. Matanoski, Chair
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Kenneth L. Dickson

Dr. Kenneth L. Dickson, Chair
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Alan W. Maki

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Enclosure

U.S. ENVIRONMENTAL PROTECTION AGENCY
SCIENCE ADVISORY BOARD
ECOLOGICAL PROCESSES AND EFFECTS COMMITTEE
WILDLIFE CRITERIA SUBCOMMITTEE

April 27-28, 1994

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U.S. Environmental Protection Agency

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Questions to Focus SAB Discussion at
SAB Commentary on
National Wildlife Criteria
3/31/94 DRAFT

Agenda Item: Characterization of Toxic Effects

Population vs. Individual Level Assessments

Wildlife criteria are intended to support risk assessments for populations of wildlife exposed to chemical pollutants. These criteria are intended to address the direct effects of chemicals on wildlife populations. They are not intended to protect individual organisms (except in special cases where that is desired) or to provide protection for wildlife habitat and associated biological communities. Used in conjunction with other criteria and diagnostic approaches, wildlife criteria provide an essential component for carrying out risk assessments at the watershed scale.

1) Given the objective of protecting wildlife populations, do you think toxicological endpoints such as mortality, growth, reproduction, and development, are appropriate for deriving criteria because they can be related, at least qualitatively, to density-independent factors which influence populations?

2) Should other endpoints such as biochemical or histopathological changes be used to support criteria development as well? Should use of these types of endpoints be restricted to cases where they can be causally-linked to mortality rates, fecundity rates, etc.?

3) Currently toxicological effects are extrapolated from NOAELs because of lack of certainty concerning the amount of increased mortality or decreased fecundity that can be absorbed in different populations and because dosing regimes in most bioassays result in very steep (i.e., "all or nothing") dose-response curves. Are you aware of any credible population dynamic models that can be used to guide selection of effect thresholds from toxicological studies?

Effects Analyses

Given the initial goal of deriving water-based wildlife criteria, a paradigm adapted from the human health non-cancer approach was generally endorsed in two separate national workshops and proposed in the Great Lakes Water Quality Initiative (GLWQI). Although based on the human health paradigm, there are significant differences between the human health and wildlife approach. Because the wildlife approach is designed to protect populations and not individuals, the wildlife paradigm does not include an intraspecies uncertainty factor (although exceptions can be made in special cases where protection of individuals is desired) and wildlife assessments are typically restricted to a smaller set of more gross endpoints. This last point is illustrated in the GLWQI assessment for DDT where the NOAELs used to calculate the mammalian wildlife value and the human health

criteria were from the same rodent bioassay. However, in the wildlife assessment the endpoint was the number of viable young per female while in the human health assessment the more sensitive endpoint of impacts on liver pathology was used.

4) Because of the limited number of toxicity tests, what is a reasonable minimum database? Should acute and/or chronic data be required?

5) Efforts are in progress to tabulate and analyze existing toxicity databases to further evaluate interspecies differences and the type and nature of chronic endpoints that are available for criteria derivation. These analyses are designed to support the development of guidance on the selection of interspecies, subchronic to chronic, LOAEL to NOAEL, and intraspecies uncertainty factors. Do you have any suggestions regarding this effort? Are you aware of additional data sources or analyses that could be used?

Allometric Scaling

To date, decisions made concerning the selection of interspecies uncertainty factors have been based on professional judgement concerning underlying toxicokinetic (i.e., absorption, distribution, metabolism and excretion rates of chemicals) and toxicodynamic (i.e., modes/mechanisms of toxic action and associated physiological and biochemical processes) principles and available empirical data. Allometric scaling (e.g.; based on surface area, $m^{2/3}$; or, physiological time, $m^{3/4}$) can be used to describe general toxicokinetic trends and contribute to "weight-of-evidence" deliberations.

6) Should allometric relationships provide the basis for the selection of an interspecies uncertainty factor or should toxicodynamic issues also be incorporated into determining an interspecies uncertainty factor? If so, how?

7) Are you aware of any other mechanistically-based toxicokinetic and toxicodynamic models that are currently available that can be employed to better predict interspecies variability?

Agenda Item: Characterization of Wildlife Exposure

Representative Species in the GLWQI Approach

One effort being conducted is to identify the most vulnerable (i.e., exposed and/or sensitive) species to contaminants in the Great Lakes to compare with the initial five species (i.e., bald eagle, osprey, kingfisher, mink, and otter) used to propose the wildlife criteria. The approach is to identify those wildlife species for which adverse impacts due to toxic contaminants have been documented in the Great Lakes region at one time or another over the past three decades. In addition to the bald eagle, osprey, mink, and otter, which have already been included in the analysis, species for which impacts have been documented include, but may not be limited to, the Caspian tern, Forster's tern, common tern, ring-billed gull, herring gull, double-crested cormorant, and black-crowned night heron. We will use dietary information and allometric equations for food ingestion rates to determine if any of these other species are likely to be more exposed to contaminants in aquatic food chains than those already included in the criteria development.

8) Is this approach adequate for defending our selection of wildlife species to examine for proposing criteria for the Great Lakes region?

9) Would this approach be appropriate for other regions of the country?

10) For areas for which adverse impacts have not yet occurred, what might be the most appropriate alternative approach?

Exposure Assessments for National Wildlife Criteria

Efforts are underway to estimate the trophic level of wildlife species that may be at risk in the Great Lakes region based on dietary studies of selected wildlife species in the Great Lakes region and elsewhere. Information on both the species and size of aquatic prey taken in specific locations is being compiled. To estimate the trophic level of the prey species, data on the feeding habits of the aquatic prey species (and the prey species' prey or forage, etc.) are being compiled from the literature. These data will be used to estimate likely trophic levels for the prey species and then for the wildlife that feed on them and to illustrate how wildlife trophic level is likely to vary by location, season, and type of aquatic ecosystem.

As part of this effort, trends in food web structure of aquatic ecosystems also are being investigated. Food web structure and potential food chain length depend on many attributes of the aquatic ecosystem and also on the history of introductions of new species to the system. For example, lakes in which *Mysis* have been introduced to "improve" the forage base for fish often have a food chain that is in effect one step longer than food chains in similar lakes in which *Mysis* has not been introduced. Also, glaciated lakes tend to support longer food chains than non-glaciated lakes in North America.

These analyses will be used for three purposes:

a) To identify the potential range and central tendencies of trophic levels for each selected species (e.g., bald eagle) in the Great Lakes Region and across the US, as well as sources of uncertainty in these estimates (which include both the wildlife feeding studies and knowledge of the aquatic food web).

b) To identify habitat attributes that are likely to influence trophic level for wildlife species, which may help define appropriate geographical regions for establishing wildlife criteria.

c) To identify key data gaps that contribute to the uncertainty in estimates of wildlife trophic levels on a site- or region-specific basis to help identify which studies (e.g., tissue residue monitoring for trout) might help most in improving estimates of water quality criteria to protect wildlife.

11) Given the highly variable nature of aquatic food chains, is analysis of site-specific wildlife diets and aquatic food webs suitable for the three purposes outlined above?

12) What other approaches should be examined to identify trophic levels for the model used to estimate water quality criteria to protect piscivorous wildlife? On a regional basis? On a more local basis?

Agenda Item: Adaptation of 1985 Aquatic Life Criteria Approach

13) We have concluded from our compilation and analysis of laboratory toxicity data that variability is so large as to made a purely statistical treatment highly uncertain and probably overconservative. Do you agree with this conclusion?

Agenda Item: U.S. Fish and Wildlife Service/National Biological Survey Approach for Dioxin-like Compounds

Use of Field Data

14) The GLWQI allows for the use of field-derived data to take precedence over laboratory data to develop a water quality criterion for a chemical. When should field-derived data on species be used to develop a criterion? What type of specific guidelines should be developed for the evaluation of field data for use in deriving wildlife criteria?

15) Can the SAB suggest a mechanism whereby information from the field and specific sites can be incorporated into the development of a wildlife criterion?

Egg-injection Studies

Egg-injection studies are useful in assessing potential reproductive/development effects, in diagnosing responses in the field, and in deriving NOAELs for avian effects assessments. In addition, many wildlife species can not be maintained in the laboratory making it impossible to conduct reproductive studies yet direct injection of the chemical into the egg provides important and relevant toxicity information. However, egg-injection studies do not incorporate potential effects of metabolism or effects on the female/male reproductive physiology or behavior. Therefore these studies could underestimate potential reproductive hazards for some modes of toxic action.

16) Are egg-injection studies appropriate for deriving NOAELs for avian effects assessments?

17) Should the use of egg-injection studies be limited to chemicals where evidence indicates the chemicals direct effects are on the developing embryo?

18) Results from egg-injection studies are being considered for use in deriving NOAELs in avian effects assessments. Although effects data from these studies can be useful from a number of perspectives, do you agree that these data are currently problematic in deriving water or sediment-based wildlife criteria because of limited bioaccumulation and toxicokinetic data that relate chemical concentrations in bird eggs to concentrations in the female bird and/or fish, sediments, or water associated with the habitat?

Mode of Action Considerations

The best example of a class of compounds which are known to have the same mode of toxic action are the dioxin-like compounds. This class includes PCBs, PCDDs, and PCDFs. The concept of assessing these using toxic equivalency factors and an additive model of toxicity has been the topic of much discussion. The conclusions have generally been that this is a

good concept, that there are examples where it has worked very well, but there are problems related to a universally applicable set of toxic equivalence factors. These is, however, a fairly large data set on avian related toxicity equivalency factors--particularly related to embryo mortality. In most instances, we know that a multiplicity of compounds are acting in concert and trying to assess them as individuals does not make sense.

19) Is the available data adequate to assess classes of compounds that act through the same toxic mode of action?

Agenda Item: General Discussion of Three Approaches

General Questions

20) Because of the paucity of data for amphibians and reptiles, wildlife criteria efforts thus far have focused on avian and mammalian wildlife species. Given current information concerning exposures and effects of bioaccumulative compounds on some species of mammalian and avian wildlife, is it appropriate to proceed with credible criteria for these taxonomic classes or should criteria/guidance be withheld until empirical databases and predictive techniques can be created for amphibians and reptiles?

21) Does the SAB have any suggestions on how best to incorporate effects on reptiles and amphibians?

22) Are approaches other than these we have presented available to relate toxicity and exposure data to derive criteria? If so, given the constraints on the availability of wildlife toxicity data, is it feasible to apply any alternative approaches to deriving wildlife criteria?

23) What is your assessment of the strengths and weaknesses of the three alternative approaches presented?

Benchmark Dose Approach

Human health non-cancer assessments are considering using the benchmark dose approach for developing RfDs for developmental endpoints in the near future. We recognize that the benchmark dose approach may provide certain advantages to the current hypothesis-testing approach (NOAEL), specifically, a LOAEL to a NOAEL uncertainty factor is no longer applicable and intraspecies variability is incorporated in the dose-response curve.

24) Should the benchmark dose approach be pursued for future wildlife criteria derivation efforts?

25) Should EPA continue with the hypothesis testing methodology or wait until the benchmark dose method is further developed?

Short-term Research Needs

In establishing a wildlife criteria approach, we have established efforts to address several near-term research needs. This includes our efforts at quantifying wildlife exposures from the aquatic food chain and compiling and analyzing wildlife toxicity data. These efforts are essential for future criteria derivation, uncertainty factor analyses, and identification and verification of critical data gaps for species-types, endpoints and modes of toxic action.

26) Are there additional short-term research efforts which we should consider?

27) Do you have any suggestions for modifications to our research priorities?

28) Do you think there is sufficient scientific consensus concerning actual or potential adverse effects of chemical stressors on wildlife to establish a formal wildlife criteria approach for inclusion in ecological risk assessments. Why or why not?

29) Based on current information, it is scientifically credible to assume that aquatic life and human health criteria for persistent bioaccumulative chemicals are necessarily protective for wildlife? Why or why not?

Currently, development of criteria is not based on all possible mammalian and avian populations, but rather on groups of avian and mammalian species which are likely to be most at risk based on species' feeding habits (exposure analyses) and the properties of the chemical. (e.g.; for highly bioaccumulative compounds which are not metabolized in aquatic ecosystems, the most exposed species would be piscivorous species which feed at higher trophic levels). If initial criteria development is based on species with the greatest exposures, subsequent analyses can be undertaken to determine if less-exposed species would be at risk based on greater sensitivity.

30) Should criteria be derived in this way, to protect populations identified as most at risk, or, should they be derived to protect a percentage of all possible species, such as is done with aquatic life criteria? (It should be noted that a percentage approach can be applied in the GLWQI approach by using a distribution of exposures for wildlife species. The toxicity database appears too limited to enable developing distributions of wildlife impacts considerate of both toxic effects and exposure assessments using the GLWQI approach.

31) Should approaches for deriving wildlife criteria be premised on the bioaccumulative potential and mode of action of the chemical of concern?

32) Should national criteria be developed based on exposure analyses of wildlife populations in the entire U.S., or should analyses be derived for smaller geographical settings in which the mammalian and avian populations most at risk can be identified (e.g., ecoregions, classes of similar watersheds, individual watersheds)?

Geographical Considerations

An alternative to providing national wildlife criteria is to provide national guidance to support criteria development in the context of specific ecoregions or smaller geographical sites (e.g., watersheds). This strategy would require a national partnership to insure that consistent approaches are used in developing criteria for similar watersheds, with similar