MEMO

DATE: November 21, 2002

TO: David R. Johnson, MD, MPH
Deputy Director for Public Health and Chief Medical Executive

THROUGH: David R. Wade, Ph.D., Director
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FROM: Linda D. Dykema, Ph.D., Manager
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SUBJECT: MDEQ Consent Order

As requested in your memo to Dr. David Wade and myself, dated November 15, 2002, I am providing my comments on the draft Corrective Action Consent Order ("Consent Order") proposed by the Michigan Department of Environmental Quality (MDEQ) for the Dow Chemical Company ("Dow") dated November 6, 2002. I am also providing additional technical details on the concerns that you raised in your memo.

Section I. Statement of Purpose, page 1

The Consent Order states that one of the purposes of the Order is to "establish the applicable environmental protection standard for the human health exposure pathways of direct human contact (including soil ingestion and dermal contact), inhalation of particulates, vegetable ingestion, and beef and dairy ingestion (referred to as the Specified Pathways") for polychlorinated dibenzodioxin and dibenzofuran isomers (hereinafter "PCDD/Fs") in residential soils in the Midland Area." There are several problems related to this statement, many of which only become apparent later in the document.

First, while it would appear that the Consent Order addresses several exposure pathways, in fact the Probabilistic Risk Assessment used to develop the applicable standard provided in Section 8.2 addresses only the direct human contact pathway and fails to quantitatively evaluate any of the others listed. Without this evaluation, it cannot be known with any certainty how these other pathways contribute to the overall health risk of exposure to dioxin contaminants. While it may reasonably be ascertained that no animal products are commercially produced within the boundaries of the city of Midland at this time, the Consent Order applies to some areas outside the city limits. No documentation of institutional control (e.g., a local ordinance) for the city or these outlying areas has been submitted to demonstrate that these pathways will not become complete in the future.

Secondly, the Consent Order mistakenly uses the term "isomer" in reference to polychlorinated dibenzodioxin and dibenzofuran compounds of interest. Isomers are chemical compounds with the same chemical composition and molecular weight, but differing structure. This description does not apply to the PCDD/Fs of concern for Midland. The correct term is "congener" meaning a member of a group of chemicals. Use of the term "isomer" could be construed to limit application of the provisions of the Consent Order only to those PCDD/Fs with chemical

application of the provisions of the Consent Order only to those PCDD/Fs with chemical composition and molecular weight identical to that of 2,3,7,8-tetrachlorodibenzo(p)dioxin (TCDD). This is a critical error.

Third, the Consent Order fails to specify which PCDD/F congeners will be addressed or which toxic equivalency factors (TEFs) will be used to convert concentrations of individual congeners to 2,3,7,8-TCDD toxic equivalents. In section 8.2, the term toxic equivalent concentrations or TEC is used in reference to the group of PCDD/Fs to which the applicable standard will apply. "TEC" is not term generally used in the scientific literature. "Toxic equivalents" or TEQ is the generally accepted term and it is not clear why the MDEQ has chosen to use a less precise term to describe the concentration of PCDD/Fs to which the applicable standard will apply. The TEFs specified by the World Health Organization (1998) should be used to determine the total TEQ concentration for comparison to the appropriate cleanup criterion for soil.

Section 8.2, page 8

The Consent Order states that 0.831 micrograms per kilogram (ug/Kg) "PCDD/Fs toxic equivalent concentrations (TEC) is the interim action level for protection of human health for the Specified Pathways for residential property soils in the Midland Area under R 299.9629 of Part 111 of NREPA." Rule 299.9629 provides for the adoption of the *cleanup criteria* developed under Part 201 of the Natural Resources and Environmental Protection Act (NREPA) for application at facilities regulated under Part 111.

Section 20120a of Part 201 provides the authority for the MDEQ to develop "cleanup criteria" based on "generic human health risk assessment assumptions." Under this authority, the MDEQ has developed a generic residential soil cleanup criterion for chlorinated dibenzodioxins and dibenzofurans of 0.90 ug/Kg or 90 parts per trillion (ppt). Nowhere in Part 201 is the term "interim action level" provided or defined. Part 201 does provide for the use of site-specific criteria under §20120a(2), however, as will be discussed below, application of a site-specific criterion dictates the need for compliance with the additional requirements provided at §20120a(16) and §20120b.

Section 8.2 of the Consent Order states that the "interim action level" is approved based on the existing sampling. It is unclear why this statement is included. Section 8.3 requires the submission of a Soil Sampling Work Plan to further characterize residential soils in the Midland Area and this additional sampling is urgently needed to ascertain dioxin levels in those residential neighborhoods in closest proximity to the Dow plant site that may be more highly contaminated than areas previously sampled.

Section 8.2 of the Consent Order cites U.S. Environmental Protection Agency (EPA) guidance documents for risk assessment and Monte Carlo Analysis. This implies that this guidance has been followed in the development of the "interim action level." No documentation has been provided to demonstrate that the Probabilistic Risk Assessment (PRA) used to develop the "interim action level" followed this guidance. In fact, as will be discussed further below, the PRA may have deviated significantly from EPA guidance.

Section 8.3, page 9

As stated in this section, the intent of additional soil sampling in residential areas in closest proximity to the Dow plant site is "to characterize residential property soil." It is unclear why,

therefore, section 8.3(e) relies upon exceedance of the interim action level to trigger confirmation sampling.

Section 8.5, pages 10-11

This section provides that the bioavailability factor determined in the *in vivo* study and approved by an outside Scientific Review Committee be used to determine a "revised interim action level" *without further review by either the MDEQ or any other state agency*. The MDEQ is essentially abdicating its authority under Part 201 to an outside entity.

This section also states that "the other information and calculations used in establishing the interim action level shall be deemed...the best available scientific information." This statement is untenable given that many of the input values used to establish the "interim action level" were decided by the upper management of the MDEQ and are in direct conflict with the majority of scientists who are knowledgeable in human health risk assessments in general and dioxin toxicity specifically. In particular, the reliance upon an outdated cancer slope factor and noncancer reference dose is troublesome and will be addressed further in my comments on the PRA.

Section 8.8, page 12-13

As indicated in your memo, this section does not mention that the draft, proposed Exposure and Health Effects Study is both DRAFT and PROPOSED. It also repeatedly refers to the study as the "Health Study" which appears to intentionally downplay the more important exposure assessment component of the study. It also indicates that the study will be performed by scientists who are unaffiliated with Dow, the MDEQ, the MDCH, the Petitioners of the Midland and Tittabawassee River flood plain Public Health Consultations, the EPA, or the Agency for Toxic Substances and Disease Registry (ATSDR). The draft proposal for the Exposure and Health Effects Study specifies only that "a university or combination of universities with recognized scientific expertise and objectivity" be selected to perform the study. It is my opinion that it will be virtually impossible to find qualified researchers who do not have *some* affiliation with at least one of these agencies, particularly the EPA or the ATSDR. It is unclear why these additional affiliation requirements have been included in the Consent Order unless the intention was to effectively preclude implementation of the study.

Section 8.9, page 13

This section gives authority to the scientists performing the Exposure and Health Study and to the Scientific Advisory Committee to dictate the necessity for immediate action to protect public health. ***This essentially hands over the responsibility and authority to protect public health and the environment delegated by state law to the MDCH and the MDEQ to nongovernmental entities.*** This is particularly troublesome given that concurrence of ***both*** the researchers and the Scientific Advisory Committee is required before any action can occur. I strongly recommend that MDCH object to the inclusion of this illegal and irresponsible language in the Consent Order.

Section 8.10, page 13

The proposed use of the Draft Proposed Exposure and Health Effects Study as a means to establish a "final action level" for residential soils is untenable and suggests a lack of understanding of the underlying science on the part of the writers of the Consent Order. The data that will be provided by the Exposure Study (e.g., dioxin blood lipid levels) cannot be factored into a Probabilistic Risk Assessment. More importantly, the rates of human health effects within

a potentially affected population cannot be used to set a soil cleanup criterion. As Dow has repeatedly stated, people are exposed to dioxins from many sources. If an individual is found to have an elevated body burden of dioxin, it will be extremely difficult to determine what relative contribution soil dioxin levels may have made to the total exposure. It will be essentially impossible to determine what concentration of dioxin in soil would not result in an elevated body burden. The focus of the Draft Proposed Exposure and Health Effects Study should be on finding those individuals who exhibit elevated body burdens of dioxin and providing an appropriate public health intervention to prevent or mitigate further exposure and lessen the impact of any potential health effects. The proposed use of this study for the purpose of setting a less stringent residential soil cleanup criterion for dioxin is contrary to MDCH's mission to protect public health and the Department should strongly object to the inclusion of this language in the MDEQ Consent Order.

Section 8.11, pate 14-15

This section states that no land-use or resource-use restrictions, except as set forth in paragraph 8.16, are necessary for or will apply to the interim action level or the revised interim action level. This is clearly contrary to state law as set forth in Part 201 of Act 451. My reasoning for this opinion follows:

Section 8.5 of the Consent Order states that the "interim action level" "is an interim site-specific criterion ...under §20120(a)(2) of Part 201 and R 299.9629 of Part 111 of the NREPA." §20120(a)(2) provides that the Department (meaning the MDEQ) may only approve a site-specific criterion if all other requirements of Part 201 are satisfied.

§324.20120a(16) of Part 201 states in part, "A remedial action plan shall provide response activity to meet the residential categorical criteria, or provide acceptable land use or resource use restrictions pursuant to §20120b." Since a site-specific criterion would not meet the residential criteria (i.e., 90 ppt in soil), land use or resource use restrictions would ordinarily be required under this section.

§324.20120b(3) states that if a remedial action is based on site-specific criterion as provided for under §324.20120a(2), then provisions concerning land use or resource use restrictions shall be stipulated in a legally enforceable agreement with the MDEQ. Further, §324.20120b(4) states that "land use or resource use restrictions...be described in a restrictive covenant. The restrictive covenant shall be recorded with the register of deeds for the county in which the property is located." This section further states, "The restrictive covenant shall be filed by the property owner or with the express written permission of the property owner." Therefore, the concurrence of the property owner is required before a site-specific closure could be effected.

The MDEQ has clearly exceeded its authority and is attempting to set aside state law by exempting Dow from the requirements for land-use restrictions specified in Part 201 of Act 451. They are attempting to impose a cleanup criterion more than 9 times the generic criterion on property not owned by Dow, without the consent of the owners and without the land use restrictions required by law to prevent people from being exposed to unacceptable levels of contaminants.

Section 8.14, page 15
No justification has been provided to demonstrate that the residential soil standard of 0.831 ug/Kg is protective for all exposure scenarios for the Specified Pathways.

Section 8.15, page 15
This section essentially leaves Dow free to propose any standard for nonresidential properties without requirements for an appropriate human health risk assessment.

Section 8.16, page 15
As in the discussion of section 8.11 of the Consent Order, the MDEQ has exceeded its authority and is attempting to set aside state law by exempting Dow from the requirements of Part 201.

a. Part 201 defines a facility as a property where "a hazardous substance in excess of concentrations which satisfy the requirements of §20120a(1)(a)...has been released, deposited, disposed of, or otherwise comes to be located." The definition does not include a property at which a cleanup that satisfied §20120a(1)(a) has been completed. Therefore, *any property at which dioxin levels exceed the 90 ppt residential cleanup criteria established under §20120a(1)(a) must be considered a facility.* The MDEQ is attempting to apply circular logic in first granting a §20120a(2) closure on property and then providing that such property not be defined as a facility under Part 201. A site-specific closure could only be effected on a property if it were first defined as a facility under Part 201; otherwise such site-specific action would be unnecessary. A property where a §20120a(2) closure is granted remains a facility by definition until such time as concentrations of hazardous substances are reduced to levels below the generic residential standards.

b. By not restricting the movement of soil within the Midland area, the MDEQ is essentially allowing soil that contains dioxins in excess of the generic residential soil criterion of 90 ppt to be relocated and *is permitting the creation of new Part 201 facilities.* This is clearly in violation of §20120c.

c. As described above, a notice on the deed for a property is required under §20120b(3) and must be disclosed to a buyer of the affected property.

Attachment 1
The Consent Order repeatedly refers to "the exposure assumptions in Attachment 1" yet this attachment merely contains a series of statements of what Dow "should" use as "factors to be used initially in a probabilistic risk assessment." Many of these statements are vague (e.g., "Dow should use the standard DEQ default value.") and do not specify either a quantitative value or a method by which a value could be derived. Many of the statements contained in this attachment are contrary to the positions formulated by the MDEQ staff toxicologists in their review of the PRA.

Calculation of a Site-Specific Soil Criterion for Midland, Michigan
This document prepared for the Dow Chemical Company by the consulting firm Exponent, contains the calculations and justification for the PRA which establishes the proposed "interim action level" of 0.831 ug/Kg or 831 ppt. I do not have the expertise to review the statistical

methods used in this assessment. However, I would like to comment on the values used to represent the toxicity of dioxins and some of the exposure assumptions used in the assessment.

Toxicity Endpoints

The use of a slope factor (SF) of 75,000 $(mg/Kg\text{-}day)^{-1}$ and a noncancer reference dose of 1.3 pg/Kg/day is not consistent with the best available science. These values are based on a daily dose of 2,3,7,8-TCDD administered in animal studies. It is the consensus of the majority of the scientific community that dioxin body burden is the appropriate dose metric for calculation of both cancer and non-cancer endpoints. This approach is supported by both the World Health Organization and the EPA and should be incorporated by the MDEQ in the development of Part 201 cleanup criteria for dioxin.

Soil Ingestion Rates for Children and Adults

The PRA uses a probability distribution function (PDF) to estimate the childhood soil ingestion rate and truncates the upper end of the distribution at 137 milligrams of soil per day (mg/day). This is contrary to EPA guidance, which recommends an upper bound average for childhood soil ingestion of 200 mg/day and a soil ingestion of 5000 mg/day for children who exhibit pica behavior. Clearly, truncating the upper end of the PDF at 137 mg/day will result in an underestimate of risk and is contrary to the purpose of a PRA, which is to represent the full range of potential exposures. The PDF is based on a single study of children in Montana and no attempt has been made to demonstrate the applicability of these data to children in Midland. The totality of the literature on childhood ingestion rates should be considered rather than a single study performed in one location.

The PRA uses a point estimate for adult soil ingestion of 50 mg/day. This value is half that assumed for the generic residential cleanup criteria developed under Part 201. No attempt has been made to demonstrate why it is assumed that the residents of Midland behave differently than other Michigan citizens. Both the childhood and the adult ingestion rates are sensitive factors in the development of a cleanup criterion and, per EPA guidance, should be set at upper end conservative values. Instead, Dow and their consultant have chosen to set these parameters at values that reflect neither EPA guidance nor the best available science.

Contribution of Other Sources of Exposure

Representatives of Dow have repeatedly stated that soil contamination represents an insignificant component of total exposure to dioxins. Yet the PRA fails to address other sources of exposure such as that know to occur through the average American diet and through local exposures to homegrown produce or fish from the Tittabawassee River. Instead, the PRA allows for ALL of an individuals permissible exposure to dioxin to occur from soil and sets the acceptable soil concentration on that basis. This is clearly inconsistent with EPA risk assessment guidance. At a minimum, consumption of homegrown produce and local fish at the rates recommended by the Michigan Fish Advisory should be factored into the PRA

This concludes my comments, however, there may be other issues in the PRA and the Consent Order that should be addressed through formal written comments. The MDCH should strongly urge the MDEQ to extend the review and comment period beyond 30 days to allow for adequate staff and public review of the Consent Order and all the associated attachments and other documents.