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Via Regular Mail and Email (OW-Docket@epamail.epa.gov)

W-99-18 NODA Comment Clerk
Water Docket (MC 4101)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Subject: EPA cannot utilize NRDC's comments on biosolids because they fail to meet the requirements of the Data Quality Act (comments on EPA's NODA and draft technical background document for dioxin and related compounds in land-applied biosolids, 67 Fed. Reg. 40554 *et seq*., June 12, 2002)

The central contention of NRDC's September 10, 2002 comments on EPA's NODA and draft TBD is that there is agreement among the scientific community, and within EPA, that current "background" levels of exposure to dioxin and related compounds pose a significant risk to both families on farms that utilize biosolids and the general population, and that therefore EPA has a legal obligation to prevent any addition to background exposures by condoning the land application of biosolids without strict regulation. The NRDC assertions are inaccurate and critically flawed.

Both the OMB and EPA guidelines make clear that information submitted to the Agency by outside parties ("third parties") must meet the same quality standards as Agency-created information in order for it to be accepted for use by EPA.[1] The NRDC comments contain so many serious inaccuracies, omissions, contradictions, and unsupported assertions, and the data and analyses they assert must be used are so inaccurate, unreliable, or biased as a basis for determining risks from biosolids, that if EPA were to use them to regulate biosolids it would be a violation of the new Data Quality requirements and would lead to filing of a Data Quality Request for Correction of any such revision of the 503/II risk assessment. Correction of any such new risk assessment would then entail another complete revision. Many of the

[1] Sec. 6.5 of EPA final guidelines; June 10 OMB/OIRA Memorandum to Agencies, citing the preamble to the OMB final guidelines, 67 FR 8457, Feb. 22, 2002.

significant flaws in the NRDC comments and the data they rely on and submit should be used by EPA in the biosolids TBD are described and discussed below.

1. Rural vs. urban background exposure levels of dioxin and related compounds

NRDC relies on "background" cancer risk estimated in the draft EPA risk assessment for dioxin and related compounds[2] (hereafter referred to as "EPA dioxin 2000"). The cancer "background" risk estimates in EPA dioxin 2000, however, are based on urban exposures to market foods and urban soil.[3] EPA's NODA and draft TBD for land-applied biosolids (hereafter "EPA biosolids 2002") are based on rural farm family exposures. Under the exposure scenario urged by NRDC, rural farm family background TEQ exposures to their amended farm soil and to farm-raised foods influenced by amended farm soil will be lower than in urban areas.[4]

Background levels of dioxin and related compounds are substantially lower in rural, compared to urban, soils, as found in EPA dioxin 2000. Typical rural background TEQ_{DF} soil concentrations were estimated as less than ¼ to ½ of typical urban levels (<5 pg/g TEQ_{DF} rural vs. 10-20 pg/g urban, or rural mean of 2.8 ppt vs. urban mean of 9.4 ppt).[5] Researchers have typically found rural TCDD and CDD/F background levels to be in the ppt range or non-detectable (with a detection range generally under 1 ppt).[6] The urban air exposure levels used for the risk estimates in EPA dioxin 2000 were also far higher than rural. Typical urban background air exposures were estimated to be 0.12 pg/m^3 vs. 0.017 pg/m^3 for rural background.[7]

2. Human exposure via dioxin and related compounds sorbed to biosolids-amended farm soil

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[2] "Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds" (Parts I-III). September 2000 SAB Review Draft (EPA/600/P-00/001Bb [Part I], Bc [Part II], and Bg [Part III]).

[3] EPA dioxin 2000, Part I, Vol. 3, at 3-2 and 3-3.

[4] The highly-exposed farm family's background exposures and risks are altered because they are assumed to consume substantial quantities of farm-raised food in place of the market foods consumed by the general population.

[5] *Id*., Part I, Vol. 3 at 5-21 and 5-27; Part I, Vol. 3 at 3-29; and see also in Part III, Table 4-5 at p. 138 (9.4 - 11.2 mean ppt urban vs. 2.5 mean ppt rural for CDD/Fs).

[6] *Id*., Part I, Vol. 4 at 2-13, 3-19.

[7] *Id*., Part I, Vol. 3 at 3-17.

vs. exposure via farm food contaminated via air deposition

Like CRE, NRDC contends that there is little or no volatilization of dioxin and related compounds from biosolids that is deposited on farm vegetation and then contaminates farm food. Rather, it contends that the dioxin and related compounds remain in the soil, and the farm family is exposed to higher risks when they contact, ingest, or inhale the soil, consume fruits and vegetables grown on the farm, or consume animals which have ingested the soil. (Pp. 14-16).

Asserting that a substantial portion of background risk and incremental exposure occurs primarily via exposure through biosolids-amended soil rather than through food lipids contaminated via air emissions creates an exposure and risk scenario that is dramatically different from that in EPA dioxin 2000 and EPA biosolids 2002. NRDC's reliance on background risk estimates in EPA dioxin 2000 is therefore misplaced, and it has not presented data and analysis to support its contentions that this new rural farm exposure scenario presents similar or higher background risks and significant incremental risks.[8] In the absence of such new data and analysis, the NRDC contentions cannot meet the reproducibility requirements of the Data Quality guidance.

3. Soil intake vs. food/vegetation intake

Not only is rural soil typically lower in background TEQ than the urban soil used for EPA dioxin 2000, but also, if, as NRDC asserts, the primary source of incremental farm family risk comes from human and animal intake of amended soil rather than air deposition of TEQ onto foods/vegetation, this would result in a further substantial decrease in the estimates of incremental risk in EPA biosolids 2002.

Compared to TEQ intake via foods, human TEQ intake via dermal contact and ingestion was estimated in EPA dioxin 2000 at less than 1% combined total exposure vs. >99% for food and water.[9]

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[8] NRDC's substantial reliance on exposure from amended soil on the farm as opposed to food exposure resulting from air and industrial emissions pathways almost completely negates its arguments concerning under-estimation of general population risks, since the general population cannot be exposed to such amended soil. Even if farm-raised food products influenced by biosolids and distributed (partially) to the general population are considered, any risks become so attenuated they are not worth considering. NRDC does not attempt to present any quantitative data that reasonably supports its assertion of under-estimation of general population risks.

[9] *Id*., Part I, Vol. 3, Table 4-49 at 4-130.

Human exposure via soil inhalation apparently was not viewed as significant and measurable.[10]

In addition, dioxin and related compounds sorbed to soil are apparently less bioavailable than such compounds in the lipid portion of foods. As noted in the previous CRE comments, the soil bond may be even tighter when soil is amended with biosolids, because the biosolids increase the *foc* (fraction of organic content) of the soil. This lower bioavailability affects both soil ingested by humans and animals and soil which comes into contact with human skin.

EPA biosolids 2002 used a bioavailability factor for soil of 65% of the bioavailability for food lipids[11], which (using NRDC's assumptions) would have to be applied to a higher level of soil vs. a lower level of food-based exposure, and which appears to be a very conservatively high level of bioavailability from soil based on data contained in EPA dioxin 2000. EPA dioxin 2000 presents data indicating bioavailability from soil more in the range of <1 to 50 percent of that for food lipids, rather than 65%[12] Application of a lower bioavailability factor to a higher amount of soil in place of food lipids would further reduce background and incremental exposures and risk estimates.

4. Obsolete data on declining levels of dioxin and related compounds in background and biosolids

NRDC claims that land-applied biosolids are "one of the most significant sources of dioxin exposure in the U.S. and will likely be an even more significant source in the future as other sources come under control." (P. 1.) This is inaccurate. It may be that NRDC was confused by failing to notice that the inventory data for land-applied biosolids in EPA dioxin 2000 had not been updated to show the substantial decreases reflected in the new EPA and AMSA survey data which became available only after EPA dioxin 2000 was released. In addition, updated sampling of human body burdens indicates further substantial declines beyond those indicated in EPA dioxin 2000.

The principal sources of dioxin and related compounds in biosolids are those that apply to background levels in soils, which are mainly air emissions from combustion and certain other industrial sources. As the emissions from those sources have declined, and as they will continue to decline in the future due to regulations promulgated in the 1990s, those decreases have been, and will increasingly be,

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[10] Much inhaled farm soil would also probably be considered "ingested" because it would be deposited in the digestive tract.

[11] EPA biosolids 2002, at 5-33, 5-34, 5-36, 5-37 and Appendix I, Table I-2.

[12] EPA dioxin 2000, Part II at 1-6 and Tables 1-1 and 1-2.

reflected in biosolids.

Despite dramatic reductions in most TEQ emission sources, EPA dioxin 2000 does not show any change in levels of TEQ in biosolids ("sewage sludge"). Table 4-2 in Part III of EPA dioxin 2000 indicated no change in levels of dioxin and related compounds in biosolids between 1987 and 1995 -- with levels remaining exactly at 79.2 g/yr TEQ_{DF} -- while most other sources were declining by close to 80 percent.

EPA dioxin 2000 obviously does not reflect the results of the new biosolids survey, NSSS 2001, reported in the NODA, which was an update of a 1988 survey, because those 2001 survey results were not available for EPA dioxin 2000. On the other hand, Table 3 of the NODA, which reflects the 2001 survey results, indicates that biosolids TEQ_{DF} has declined by between roughly 60 and 90 percent (depending on percentile of samples -- 89% decline at the 95th percentile) between 1988 and 2001. This is what would be expected from the declines in other sources which contribute to levels in biosolids. EPA/ORD has informed CRE that it is currently in the process of updating the dioxin inventory in EPA dioxin 2000 to reflect new estimates for land-applied biosolids. When the new information on TEQ levels in biosolids is reflected in the dioxin inventory, it is very unlikely that land-applied biosolids will be seen as representing a significant contribution to either background or incremental risk.

It can be expected that TEQ levels in biosolids will continue to decline with ongoing declines in emissions from other sources. It can also be expected that such declines from all sources will result in lower background soil levels and human intakes and body burdens, resulting in lower estimates of background and any incremental risk. The most recent estimate of human (urban) TEQ intake contained in EPA dioxin 2000, which was based on mid-1990s tissue level data[13], is 0.93 pg/kg/day (sometimes rounded by EPA to 1.0), based on total intake of 65 pg/day.[14] Current average human body burdens are estimated at about 25 pg TEQ/g lipid.[15] The body burden levels in the late 1980s and early 1990s were estimated at 55 pg TEQ/g lipid.[16] Since estimates of current body burdens are based on past exposures, and exposures have been declining and are expected to continue to decline, future body burdens will be

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[13] EPA dioxin 2000, Part III at 113.

[14] *Id*., Table 4-3 at 140. It should be kept in mind that these intake estimates are for an urban population, and therefore they are higher than would be expected for a rural farm family.

[15] *Id*. at 70.

[16] *Id*. The EPA draft found that modeling suggested that peak infant body burdens are only about 2 times current adult body burdens, with such burdens expected to decline in the future. *Id*. at 75.

substantially lower. Even if current intake levels of roughly 1 pg/kg/day are assumed to continue, body burdens would decline very substantially into the <2 ng/kg region.[17] However, intake levels are expected to continue to decline, and, as pointed out previously, even the "current" intake levels used in EPA dioxin 2000 were from blood samples taken in the mid-1990s and are outdated.

Human tissue sampling data just released by CDC on January 31, 2002[18], as well as the recent modeling by Aylward and Hays, 2002[19], reflect continuing decreases in background human intake and body burdens.

Aylward and Hays examined tissue and food sampling data up to 2000, and then modeled intake and body burden levels. They estimated current average background intake of TCDD at 0.04 pg/kg/day, which would translate to roughly a TEQ_{DFP} intake of 0.4 pg/kg/day compared to the EPA dioxin 2000 estimate of 1.0 pg/kg/day. (At 326.) This would indicate a lagging future body burden of less than 1 ng/kg TEQ, compared to the 10-50 ng/kg background body burdens used as the basis for risk assessment in EPA dioxin 2000.

The just-released CDC report, which was based on human sampling from 1999-2000, found that most blood samples had undetectable levels of TCDD (with a detection limit of 4.5 pg/g lipid).

NRDC's comments do not take into account this time-trend exposure data and modeling, and they do not present any alternative data or modeling that would support their contention that strict regulation is needed to avoid significant risks for the future.

5. Reliance on the cancer slope factor and hazard classifications in EPA dioxin 2000

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[17] The June 2000 draft of Part III of EPA dioxin 2000 contained an estimate of such future body burdens based on the same current intake estimates contained in the September 2000 SAB review draft. The June 2000 draft stated: "If the general population were exposed to dioxins and related compounds at the current level of intake (approximately 1 pg TEQ/kg/day) for a lifetime, average steady-state body burdens would be <2 ng/kg and blood levels would be 7-8 pg TEQ/g lipid." At 96. This statement and calculation appear to have been removed from the September 2000 SAB review draft.

[18] *Second National Report on Human Exposure to Environmental Chemicals*. January 2002. CDC, NCEH Pub. No. 03-0022. P. 5 in Summary, and pp. 97-118 in the body of the report.

[19] Aylward LL and Hays SM. 2002. Temporal trends in human TCDD body burden: Decrease over three decades and implications for exposure levels. *J Expos Analysis & Environ Epidem* 12(5):319-28.

NRDC argues that EPA must use the cancer slope factor in EPA dioxin 2000 because it represents the best available science, because the EPA Science Advisory Board approved of that cancer slope factor, because there is no safe level of exposure to dioxin and related compounds, and because there is agreement in the scientific community that background levels of dioxin are already at levels that pose a risk to human health. None of these assertions can be supported as accurate, and EPA dioxin 2000 cannot be considered to represent the best available science.

It should almost go without saying that because EPA dioxin 2000 is a draft which was submitted to the SAB for review, it does not represent the final views of the Agency. That fact is stated prominently right on its cover.

One of the key aspects of EPA dioxin 2000 with which the SAB could not agree was EPA's use of linear low-dose extrapolation and its cancer slope factor (also "potency factor"). What the SAB did conclude was that the shape of the dose-response could not be determined, and that it could not agree on a single potency factor.[20] (P. 6.) The SAB report observed that about half the Members believed that accepted receptor theory would indicate a threshold cancer response rather than a non-threshold linear response. (Pp. 55, 37-38.) The SAB also noted that the Agency used the same slope factor for all components of the TEQ, and that this was based on assumption rather than data. (P. 29.) Furthermore, with regard to the animal evidence, the SAB noted that the rodent data appeared to indicate a reduction in overall cancer risk at the lower dose levels, and advised EPA to acknowledge that reducing current body burdens of TCDD might lead to no change at all in cancer incidence, or even a net increase." (P. 50.)[21]

Finally, a majority of the SAB could not agree that TCDD should be considered a "known human carcinogen" (even at extremely high exposures), and a majority also could not agree with the Agency that the TCDD-related compounds comprising the remainder of the TEQ should be considered "likely" human carcinogens. (Pp. 4 & n.6, 46.) This is especially important because EPA dioxin 2000 estimates that only about one-tenth of the TEQ exposure (that is the total exposure from dioxin and related compounds) is contributed by TCDD.

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[20] *Dioxin Reassessment – An SAB review of the Office of Research and Development's Reassessment of dioxin*. EPA-SAB-EC-01-006, May 2001.

[21] With regard to the epidemiologic data on cancer, the SAB, contrary to NRDC, "raised significant concerns about whether the document [EPA dioxin 2000] incorporated the epidemiological data into cancer risk assessment in a scientifically appropriate manner." P. 42.

It is important for judging the Data Quality compliance of EPA dioxin 2000 that it did not receive peer review approval on key points such as these, and that the SAB peer reviewers recognized that the Agency's use of linear low-dose extrapolation, its cancer slope factor, and its cancer hazard classifications were based on policy defaults – *i.e.*, policy biases – rather than objective scientific judgment. EPA dioxin 2000 cannot be considered to be the "best available science"and be widely accepted by the scientific community when it has not been revised in accordance with the peer review recommendations of its Science Advisory Board; and its use of policy bias in the draft risk assessment is contrary to the Data Quality law.

6. Unreliable estimates of non-cancer risks

The NRDC comments insist that EPA dioxin 2000, and the data it contains, indicate that there are serious non-cancer risks close to current human background levels, and that, like the Agency draft cancer risk estimates, this information must be accepted as the best available science.

This again is not accurate. EPA dioxin 2000 does not contain a quantitative estimate of non-cancer risks, and both it and the SAB review note that there is little if any evidence of non-cancer effects in human populations that have been accidentally exposed to very high levels of dioxin. The SAB was of the opinion that the non-cancer database was inadequate to allow for reliable low-dose quantitative estimates. (P. 7.) The SAB also found it difficult to justify the Agency's use of body-burden as the appropriate dose measure for reproductive and developmental endpoints, as opposed to timing and magnitude of exposure (which played a key role in the animal experiments). (P. 18.)

As discussed below, other agencies which have evaluated dioxin and TEQ risks have reviewed the more recent animal data on non-cancer effects and have adopted a different assessment approach which has led them to set risk thresholds which are well above current intakes and body burdens (particularly for farm families), and even higher than anticipated future intakes and body burdens. The SAB was clearly concerned about this, particularly as to why EPA's approach appeared to differ from those of ATSDR[22] and the World Health Organization (WHO). The SAB stated that "EPA does need to offer a clear explanation of why they are differing from the conclusions of other US and international agencies that have taken official positions on TCDD." (P. 21.)

7. Views of the scientific community outside EPA on risk levels for dioxin and related compounds

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[22] The Agency for Toxic Substances and Disease Registry, which is part of the U.S. Department of Health and Human Services.

The risk estimates in EPA dioxin 2000 do not reflect the views of the wider scientific community. Recommended intake levels for minimal risk recently developed and adopted in final form by a number of US and international agencies are substantially higher than those implied by the EPA estimates, and take into account the most recent non-cancer studies and apply ample uncertainty factors based on scientific judgment.

- **WHO-IPCS**: In May 1998, an Expert Consultation was organized by the World Health Organization's European Centre for Environment and Health together with the International Programme on Chemical Safety (IPCS[23]). The WHO-IPCS Consultation focused on the most sensitive reproductive and developmental effects seen at low doses in animal studies. The experts applied a 10-fold uncertainty factor to arrive at a tolerable daily intake (TDI) of 1-4 pg TEQ/kg/day.[24]

  The lower end of this 1-4 pg range is more than twice as high as typical current intake levels of 0.4 pg/kg/day (based on sampling in the late 1990s) estimated recently by Aylward and Hays (*supra*). Even EPA's draft estimated background daily intake, which is based on sampling from the mid-1990s, is below the lower end of the range at 0.93 pg TEQ/kg/day. The current time trend of reduction in background exposures and specific releases will result in future intake levels significantly lower than 0.4 pg/kg/day.

- **ATSDR**: In December 1998, ATSDR (U.S. Dept. of Health and Human Services) published a Toxicological Profile for dioxins.[25] It set a chronic MRL (minimal risk level) of 1 pg/kg/day, based on the lowest possible observed non-cancer effect (altered social interactions with peers among monkeys) and use of three uncertainty factors for a total UF of 90x.

- **European Commission**: In May 2001, the EU's Scientific Committee on Food conducted a risk assessment of dioxins and related compounds in food to update its November 2000 opinion. It adopted a Tolerable Weekly Intake (TWI) of 14.0, which translates into 2.0 pg TEQ/kg/day. The Committee employed a 9.6x overall uncertainty factor to the latest data on reproductive and immune system effects in the offspring of pregnant rats exposed to TCDD, and endometriosis in

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[23] IPCS is a collaborative program of the United Nations Environment Programme, the International Labour Organization, and the World Health Organization.

[24] van Leeuwen FX, Feeley M, Schrenk D, Larsen JC, Farland W, Younes M. 2000. Dioxins: WHO's tolerable daily intake (TDI) revisited. *Chemosphere* 40(9-11):1095-101.

[25] *Toxicological Profile for Chlorinated Dibenzo-p-Dioxins* (Dec. 1998).

monkeys.[26]

- **JECFA (FAO/WHO)**: In June 2001, the Joint FAO/WHO Expert Committee on Food Additives[27] (JECFA) adopted a Provisional Tolerable Monthly Intake of 70 pg/kg/mo., which translates to 2.3 pg/kg/day. The PTMI was based on reproductive and immune system effects in the male offspring of prenatally exposed maternal rats. The Committee applied two safety factors for an overall safety factor of 9.6.[28]

- **Individual Countries:** Austria, Germany, Italy, The Netherlands, and the UK have adopted TDIs of 10 pg/kg/day. Denmark, Finland, and Sweden have adopted TDIs of 5 pg/kg/day. France has a TDI of 1 pg/kg/day.[29]

8. Degree of "conservatism" in the model farm scenario and risk estimates

NRDC argues that the model farm scenario used in EPA biosolids 2000 is not sufficiently conservative. As CRE pointed out in its initial comments, there are prominent aspects of the scenario that are already overly conservative. One of these is the assumption that the highly exposed farm family consumes large aggregate amounts of biosolids-contaminated foods in the form of farm-raised fruits and vegetables, beef, dairy, chicken, eggs, and fish. Even EPA dioxin 2000 considered such an aggregation of on-farm food sources to be unreasonable.[30] EPA guidance calls for the use of reasonable maximum exposure, not extreme exposure.

A number of the NRDC arguments, such as assertions that the amount of soil ingested by cattle is under-estimated, and that exposure of infants and adults to amended soil has been under-estimated, lead

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[26] *Opinion of the Scientific Committee on Food on the Risk Assessment of Dioxins and Dioxin-Like PCBs in Food* (CS/CNTM/Dioxin/20 final, 30 May 2001).

[27] FAO is the Food and Agricultural Organization of the United Nations.

[28] *Summary of the Joint FAO/WHO Expert Committee of Food Additives Fifty-seventh meeting, Rome, 5-14 June 2001*.

[29] *Compilation of EU Dioxin Exposure and Health Data: Summary Report*. (Produced by AEA Technology for the European Commission Directorate General Environment, Oct. 1999, Report AEAT/EEQC/0016).

[30] See EPA dioxin 2000, Part I, pp. 2-12 and 5-6 to 5-7.

back to its argument for a soil-based exposure model, which in turn appears to result in a net reduction in human exposure and risk estimates.

Other arguments, such as that EPA ignored the possibility of consumption of fish from farm ponds and possible contamination of groundwater by amended soil, are too far-fetched to be considered in a reasonable maximum exposure model. For example, in order to consistently produce edible fish in sufficient quantities, farm ponds generally require considerable management and certain minimum physical characteristics (such as a sufficient depth and water quality) which are rare and require considerable effort to maintain.[31] With regard to the potential for groundwater contamination, soil particles to which dioxin and related compounds are adsorbed do not generally migrate from the surface to well-water depth so as to pose a concern. NRDC did not present data to support the reasonableness of such modeling scenarios, and therefore they cannot be regarded as soundly based.

Summary and Conclusions

The principal assertions by NRDC are not supported by the data and do not meet the requirements for third-party data in the Data Quality guidance of OMB and EPA:

1. The weight of the scientific evidence indicates that current background exposures to dioxin and related compounds do not present any significant cancer or non-cancer risks. Additionally, background exposure levels are substantially lower for rural farm families using biosolids as compared to the urban populations assumed in EPA dioxin 2000, and all exposure levels are expected to continue to decline and are already well below the minimal exposure levels adopted by other U.S. and international agencies as final positions.

2. NRDC's reliance on farm soil exposure pathways in place of food lipid exposure pathways appears to result in a reduction in potential incremental risk. NRDC has not provided data, analysis, and modeling to support this radically different exposure scenario and its assertion that it results in higher risks that would meet Data Quality requirements.

3. NRDC's reliance on EPA dioxin 2000 ignores the draft status of the 2000 reassessment and the SAB peer reviewers' serious disagreements with key aspects of the draft reassessment.

4. Many of NRDC's arguments are based on asserted need to inject policy bias into the risk

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[31] See Swensen W, Nichols S, Craven S, Malison J, Thrall T, Marcquenski S, and Peterson JO. 2000. *Managing Wisconsin Fish Farms.* (Univ. of Wisconsin Pub. G3693).

assessment, which would be a violation of Data Quality requirements.

When all of the above Data Quality flaws and deficiencies in the NRDC comments are taken into account, it becomes even clearer that any incremental cancer or non-cancer risk from land-applied biosolids, and any rural background risks from biosolids, are probably considerably lower rather than higher than estimated in EPA biosolids 2002 and the NODA, and are clearly insignificant.

Use by EPA of the NRDC information and assertions would violate Data Quality requirements and lead to filing of a Request for Correction by CRE and ultimately the need to reject those positions.

Thank you for consideration of these comments.

Respectfully,

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