# SIELKEN, INC. <br> Statistical Research \& Consulting 

Suite 230 3833 Texas Avenue Bryan, Texas 77802 409-846-5175
Facsimile: 409-846-2671

Robert L. Sielken Jr., Ph.D.
Biostatistician President

May 25, 1995

Ms. Sylvia Amaya
Texas Natural Resource Conservation Commission P.O. Box 13087

Austin, Texas 78711-3087
Re: State of Texas Environmental Priorities Project (STEPP):
Review of "Lawn Care Chemicals: Human Health Risks"

Dear Ms. Amaya:

Per your request, I have prepared the following comments addressed to the authors of "Lawn Care Chemicals: Human Health Risks":

TNRCC Question 1. Is the report understandable by an educated reader?
Comment 1.

The report is well organized, well written, and really a good report.
Comment 2.

In evaluating the potential for adverse health effects, the report quite appropriately focuses on the magnitude of the dose of the chemical.

Comment 3.


#### Abstract

Also, quite appropriately, the report focuses on risks and benefits, short and llong term effects, and both populations and different sensitive subbpopulations.


## Comment 4.

The report does make relatively worst case assumptions and 1 believe makes this fairly clear. Nevertheless, it is important that readers not mistake these assumptions as reality or the best estimates available: For instance, adverse health effects do not necessarily occur whenever a dose exceeds an RiD. Nor do the RiDs calculated using techniques with a tendency to underestimate dose levels with essentially no adverse effects represent the best, most complete description of such doses.

A meaningful comparison between exposures to 20 selected active chemical ingredients and their corresponding reference doses presupposes the validity of those reference doses. The derivation of reference doses from NOAELS (or LOAELS) in animal experiments has well documented shortcomings [see, for example, Lu, F.C. and Sielken, R.L. Jr., "Assessment of Safety/Risk of Chemicals: Inception and Evolution of the ADI and Dose-Response Modeling Procedures", Toxicology Letters, 59 (1991), pp.5-40. Leisenring, W. and Ryan, L., "Statistical Properties of the NOAEL", Regulatory Toxicology and Pharmacology, 15 (1992), pp. 161-171.J: The experimental dose level immediately below the lowest dose that produces a "statistically or biologically" significant increase may not be as appropriate as a benchmark dose. The safety factor(s) used to reduce the NOAEL, LOAEL, or benchmark dose to an RfD often compounds conservatism to an extreme degree and the default choices of powers of 10 may not be the most appropriate choices.

Comment 5. Minor typographical errors
a) Should not the "A" and "B" indicators be on the same line as the numbers in Table 4?
b) Pollution is misspelled on page 13 , line 49
c) Footnote 5 on page 4 line 44 should be Footnote 4 .

## Comment 6.

It would be helpful to the reader if Scenario $A$ and $B$ were more clearly defined. I made the following assumptions about what Scenario A and B were but could not find precise wording to confirm my assumptions or to correct any mistakes in those assumptions.

I assumed that in Scenario A, for say Insecticides, that 9 ECs were calculated -- one for each of the nine chemicals in the group of insecticides -- and then the maximum of these 9 values was taken as the EC for Insecticides under Scenario A. In each of the nine calculations, the : chemical was assumed to treat the entire target area.

I assumed that in Scenario B, for say Insecticides, that 9 ECs were calculated -- one for each of the nine chemicals in the group of insecticides -- and then the maximum of these 9 values was taken as the EC for Insecticides under Scenario B. In each of the nine calculations, the chemical was assumed to treat 1/9-th of the entire target area and the resulting concentrated was averaged 'out over the entire target area (thereby, making the final residual concentration equal to $1 / 9$-the of the initial residual concentration in the area in which that one insecticide was applied).

Please provide additional clarification.

TNRCC Question 2. Did the report address the criteria used for ranking?
Comment 7.

Answer is primarily "Yes" as follows:
Probability: may be very low -- page 14, line 47
Severity:
variety -- page 5, line 37
low except maybe for sensitive subpopulations -- page 17 , lines 6-8

Adversity: Unlikely -- page 5, line 42

## Population Affected:

$15-20 \%$ of population -- page 1 , lines $26 \& 29$
$10-12 \%$ of population might be a hypersensitive subpopulation -- page 15, line 13

## Uncertainty:

upper bounds were low, so distributional and quantitative analyses of uncertainty impacts not explicitly evaluated

## TNRCC Question 3. Does the report enable the reader to characterize the risk?

## Comment 8.

The report essentially does a screening analysis. This analysis makes several worst-case assumptions and finds that even under these assumptions the human health risks are probably very low. I would assume that if this had not been the answer, the authors would have followed up on their initial screening analysis with a more detailed analysis. Several of the following would have been appropriate in such a higher tier analysis if it would have been needed.
a.) Distributional characterizations of dose levels in which probability distributions would have been used to describe the frequency or relative likelihood of such things as use rates, the parameters in equation (10) on page 8 beginning on line 3 , and the parameters in the TCL formula on page 13 beginning on line 11.
b.) Weight-of-evidence analyses of the reference dose values for specific chemicals incorporating alternative no-observed-adverse-effect levels, lowest-observed-adverse-effect levels, and benchmark doses as well as distributional characterizations of the uncertainty/safety factors and other alternatives to the powers of 10 frequently used to generate lower bounds on a dose that is unlikely to produce adverse health effects.
c.) Weight-of-evidence analyses incorporating all of the available evidence and the current state of knowledge on the added cancer risks in humans at different doses as well as possibly distributional

## APPENDIX 1 <br> PAIRWISE COMPARISONS

The following pages in this Appendix list the pairwise comparisons the Human Health Workgroup voted on to arrive at the final ranking at the February 22, 1995 ranking meeting. Pairwise comparisons are listed in terms of Issue number. The issues to which these numbers correspond are provided:

1. Global Climate Change
2. Water Availability
3. Surface Water Quality
4. Pesticide Contamination
5. Indoor Air Pollution
6. Waste*
7. Stratospheric Ozone Depletion
8. Lead Contamination
9. Public Drinking Water Quality
10. Flooding
11. Groundwater Quality
12. Toxics in the Home
13. Lawn Chemicals
14. Particulate Matter
15. Air Toxics
16. Ground-level (Smog) Ozone
17. Food Safety
18. Pests
19. Electromagnetic Fields
20. Radiation
*The Waste Issue was not ranked at the February 22 meeting, so when comparisons with the Waste Issue were presented, the other issue was always recorded as posing the greater risk. Thus, Waste was artificially "ranked" the lowest of all issues.

| 1. | Does 5 pose a greater risk than $15 ?$ | Yes |
| ---: | :--- | :---: |
| 2. | Does 15 pose a greater risk than $16 ?$ | No |
| 3. | Does 5 pose a greater risk than $16 ?$ | Yes |
| 4. | Does 16 pose a greater risk than $15 ?$ | Yes |
| 5. | Does 16 pose a greater risk than $14 ?$ | No |
| 6. | Does 5 pose a greater risk than $14 ?$ | Yes |
| 7. | Does 14 pose a greater risk than $16 ?$ | Yes |
| 8. | Does 16 pose a greater risk than $2 ?$ | No |
| 9. | Does 14 pose a greater risk than $2 ?$ | Yes |
| 10. | Does 2 pose a greater risk than $16 ?$ | No |
| 11. | Does 16 pose a greater risk than $8 ?$ | Yes |
| 12. | Does 15 pose a greater risk than $8 ?$ | No |
| 13. | Does 8 pose a greater risk than $15 ?$ | Yes |
| 14. | Does 16 pose a greater risk than $13 ?$ | Yes |
| 15. | Does 8 pose a greater risk than $13 ?$ | Yes |
| 16. | Does 15 pose a greater risk than $13 ?$ | Yes |
| 17. | Does 8 pose a greater risk than $20 ?$ | Yes |
| 18. | Does 13 pose a greater risk than $20 ?$ | No |
| 19. | Does 15 pose a greater risk than $20 ?$ | Yes |
| 20. | Does 20 pose a greater risk than $13 ?$ | No |
| 21. | Does 8 pose a greater risk than $3 ?$ | Yes |
| 22. | Does 13 pose a greater risk than $3 ?$ |  |
| 23. | Does 15 pose a greater risk than $3 ?$ | Yes |
| 24. | Does 3 pose a greater risk than $13 ?$ | Yes |
| 25. | Does 8 pose a greater risk than $6 ?$ |  |
|  |  | N |
| 16 |  |  |


| 26. | Does 3 pose a greater risk than 6 ? | Yes |
| :---: | :---: | :---: |
| 27. | Does 13 pose a greater risk than 6 ? | Yes |
| 28. | Does 15 pose a greater risk than 1 ? | Yes |
| 29. | Does 6 pose a greater risk than 1 ? | No |
| 30. | Does 3 pose a greater risk than 1 ? | Yes |
| 31. | Does 13 pose a greater risk than 1 ? | No |
| 32. | Does 1 pose a greater risk than 13? | Yes |
| 33. | Does 15 pose a greater risk than 11 ? | No |
| 34. | Does 8 pose a greater risk than 11 ? | Yes |
| 35. | Does 11 pose a greater risk than $15 ?$ | Yes |
| 36. | Does 15 pose a greater risk than 12 ? | Yes |
| 37. | Does 1 pose a greater risk than 12 ? | Yes |
| 38. | Does 6 pose a greater risk than 12 ? | No |
| 39. | Does 13 pose a greater risk than 12 ? | No |
| 40. | Does 12 pose a greater risk than 13? | No |
| 41. | Does 15 pose a greater risk than 9 ? | Yes |
| 42. | Does 12 pose a greater risk than 9 ? | No |
| 43. | Does 1 pose a greater risk than 9 ? | Yes |
| 44. | Does 9 pose a greater risk than 12 ? | Yes |
| 45. | Does 15 pose a greater risk than 10 ? | Yes |
| 46. | Does 9 pose a greater risk than 10 ? | Yes |
| 47. | Does 12 pose a greater risk than 10 ? | Yes |
| 48. | Does 6 pose a greater risk than 10 ? | No |
| 49. | Does 10 pose a greater risk than 6 ? | Yes |
| 50. | Does 3 pose a greater risk than 17 ? | No |


| 51. | Does 11 pose a greater risk than 17? | No |
| :---: | :---: | :---: |
| 52. | Does 8 pose a greater risk than 17? | Yes |
| 53. | Does 17 pose a greater risk than 11 ? | No |
| 54. | Does 3 pose a greater risk than 18 ? | Yes |
| 55. | Does 10 pose a greater risk than 18? | Yes |
| 56. | Does 6 pose a greater risk than 18 ? | No |
| 57. | Does 18 pose a greater risk than 6 ? | Yes |
| 58. | Does 3 pose a greater risk than 19 ? | Yes |
| 59. | Does 18 pose a greater risk than 19 ? | Yes |
| 60. | Does 6 pose a greater risk than 19? | No |
| 61. | Does 19 pose a greater risk than 6? | Yes |
| 62. | Does 1 pose a greater risk than 4 ? | Yes |
| 63. | Does 19 pose a greater risk than 4? | No |
| 64. | Does 18 pose a greater risk than 4? | No |
| 65. | Does 10 pose a greater risk than 4? | No |
| 66. | Does 9 pose a greater risk than 4 ? | Yes |
| 67. | Does 12 pose a greater risk than 4 ? | No |
| 68. | Does 4 pose a greater risk than 12 ? | Yes |
| 69. | Does 1 pose a greater risk than 7 ? | Yes |
| 70. | Does 4 pose a greater risk than 7 ? | No |
| 71. | Does 9 pose a greater risk than 7 ? | No |

