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TSCA/SEC 8(c)

TO: Distribution

FROM: T. G. Grumbles
DATE: May 28, 1987

SUBJ: TSCA SECTION 8 PROCEDURES

VISTA

Interoffic Communication

This memo is to reemphasize and update the Vista Section 8 procedures. Posters for in-plant use and forms for use in recording Section 8(c) and 8(e) allegations are enclosed. A copy of the 8(c) regulation and a summary of Section 8(c) are also included for your reference. Some key points are below.

1. Section 8(c) requires the recording of allegations, that a chemical substance has caused harm to humans or the environment. Allegations are "statements made without formal proof or regard for evidence".

2. The only allegations not recordable are those that are known health effects. Known health effects are defined in the regulation (717.3(c)(i)).

3. The 8(c) corporate file is kept in Houston Environmental.

4. Houston will review the Section 8 allegations to determine the extent of any follow-up investigation needed. This investigation will assure the disposition of the allegation as indicated on the back page of the long form.

To illustrate EPA's enforcement activity in TSCA Section 8 matters a recent BNA article is enclosed.

Additional forms and posters are available in Houston if needed.

T. G. Grumbles

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Attachments

DISTRIBUTION: Environmental Coordinators
Safety Directors

cc W. L. McClain

VEV-141283

~~Response~~ A

File-370

CHEMICAL MANUFACTURERS ASSOCIATION

VIA FEDERAL EXPRESS
May 1, 1991

TO: Ad Hoc TSCA 8(e) Group
Health and Safety Committee
Chemical Reporting Task Group
Chemical Control Task Group
Chemical Testing Task Group

RE: Draft Case Studies to Clarify Reporting Requirements for TSCA Section 8(e) and the CAP

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FOR IMMEDIATE ATTENTION

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Enclosed FOR YOUR IMMEDIATE REVIEW are the draft case studies developed at last weeks working sessions. Each one is at a different stage of development and some follow the outline we established more than others. I suggest we work towards following this outline as much as posible and a copy of it is enclosed for reference as you review the cases.

To keep with our intention of submitting them to EPA as early next week as possible (ideally they will be submitted on Monday, May 6), I will need your comments ASAP, with an absolute deadline of 9:00 A.M. Monday, May 6. Please fax your comments to my direct attention at 202/887-1282. If additional work is needed, I will contact the discussion leaders from last week's sessions. Thanks again for all your help.

Sincerely,

Kathryn A. Rosica
Director
Health and Safety

Enclosures

cc:
S. Conti, CMA
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VEV-141292

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Attachment I
April 19,1991

TSCA Section 8(e)
Compliance Audit Program
Draft Outline for Case Studies

Section I: Study Specific Information

This section will detail the information specific to the study/report in question. Information on the type of material tested, study purpose and design, and study results that are relevant to consider in evaluating reportability should all be included.

Section II: Other Relevant Information

This section will describe other information that is relevant to consider in evaluating study results. This could include information on structurally similar materials, current or anticipated uses, exposure potential, magnitude of the available database on the material, etc. In some cases (particular health effects endpoints) it may not be appropriate to consider any additional information relevant; if so, this should be stated. In other cases, there will be extensive information that is appropriate to consider. If there is information that has already been 'made available' to EPA (non TSCA 8e), it would be appropriate to include it in this section.

Section III: Existing EPA Guidance

This section will discuss existing Agency guidance on the reportability of the study results. The guidance should be specifically referenced, and if no guidance is available, it should be stated as such. Relevant Agency guidance that should be reviewed include guidance specific to TSCA 8(e), i.e., 1978 Policy Statement, two Q & A's, the subpoena letters (others? which ones?), as well as Agency guidance that has been published for other programs, such as RCRA, FIFRA, CWA (others?). If guidance over time appears to be contradictory, this should be explicitly discussed.

Section IV: Evaluation Discussion

This section will, in essence, be 'the answer', but careful discussion of all relevant information should be included. {While not yet discussed, it may be a good idea to include cases where the discussion supports submitting the study, and cases where the discussion leads to a conclusion that immediate reporting is unnecessary.

Section V: Magnitude of Study Type

This section will generally describe the relative frequency of these kind of studies and/or results, in order to place 'substantial risk' reporting in the proper perspective.

Section VI: Conclusion

This section will have a very clear and concise response to the question of reportability.

VEV-141293

HEALTH Effects Case Studies

(Cases 1 -> 8)

CASE STUDY 1:

ACUTE STUDIES /

Numerical Cut offs

1ST DRAFT

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TSCA SECTION 8(e)
COMPLIANCE AUDIT PROGRAM

CASE STUDY: NUMERICAL CUTOFFS

Section I: R&D Chemical; Pesticide Candidate

An acute oral(gavage) LD50 study was conducted in male rats. Following administration of the test material, rats were observed for 14 days for clinical signs of toxicity. At the end of this observation period, all surviving rats were sacrificed and examined for gross pathological changes. Rats found dead were also subjected to gross pathological examination.

The oral LD50 was calculated to be 40 mg/kg; transient non-specific clinical signs were observed in all treated rats. Gross pathology revealed nothing unexpected.

Section II: Other Relevant Information

2. The R&D material has been synthesized in small quantity (<5 gm) and has always been handled within a fume hood.

Section III: Existing EPA Guidance

Agency guidance [EPA 1978 8(a) Statement of Interpretation and Enforcement Policy; 43 FR 11110 (March 16,1978)] states that information that shows a tested chemical to be extremely toxic (eg. causes lethality at very low doses) by, for example inhalation, dermal application or oral administration should be reported.

Section IV: Evaluation/Discussion

EPA in its 1978 Policy Statement refers to three categories, namely, extremely, moderately, and slightly or minimally toxic. There are numerous classification schemes which have been published (eg. EPA FIFRA, TSCA SNUR, EEC 6th Amendment for Classification and Labeling, United Nations Transportation Criteria, SARA Section 302, OSHA, DOT, Casserett and Doull, Deichmann and Gerarde etc.). There is some variation amongst the classification schemes and several which differentiate between extremely toxic and highly toxic. Several of those which differentiate between extremely and highly toxic use a cut-off of less than or equal to 25 mg/kg (oral LD50).

CMA strongly believes that the Agency should consider domestic/national consistancy as well as international harmonization. This would minimize the number of inconsistant written notifications that by law must be submitted and reduce reporting errors. In addition, verbal guidance from EPA to numerous companies and industry associations has been consistant with a cut-off of less than or equal to 25 mg/kg for oral administration.

VEV-141296

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Section V: Magnitude of Study Type

???????

Section VI: Conclusion

In the above case study, the information would not be considered reportable under TCSA Section 8(e) criteria for the following reasons. First, the threshold for "extremely toxic" is considered to be less than or equal to 25 mg/kg (oral) by several sources [eg. SARA; SNUR; EEC] which differentiate between extremely and highly toxic. While we are aware of other schemes that use less than or equal to 50 mg/kg (oral) as highly toxic, EPA should not equate this to extremely toxic.

Regarding dermal and inhalation toxicity testing, similar arguements can be made for each type of testing. The numberical cut-offs we believe would constitute reportability as "extremely toxic" are as follows:

Oral LD50	less than or equal to 25 mg/kg
Dermal LD50	less than or equal to 50 mg/kg
Inhalation LC50	
Vapors	less than or equal to 0.5 mg/L
Aerosols/Particulate	less than or equal to 2 mg/L

References:

SARA Emergency Planning and Community Right-To-Know Programs, 51 FR 221, 11/17/86, 41570-41580.

TSCA Section 5(a) Significant New Use Rule (SNUR) 52 FR 82, 4/29/87, 15603-15604.

79/831/EEC, Council Directive 9/18/79, Amending for the 6TH Time 67/548/EEC.

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CASE STUDY 2

Acute Studies -

Limit Test -

Neurotoxicity

Human Health Effects Case Study
Acute Toxicity - Limit Test - "Neurotox"

Draft 3 - 4/29/91

I. Study Specific Information

The purpose of this case study is to describe the critaria necessary to assess the reportability of acute toxicity tests under TSCA 8(e) that contain various signs and symptoms that might be indicative of neurotoxicity.

A company conducts acute toxicity limit testing (oral dose is 2000 mg/kg; dermal dose is 2000 mg/kg; inhalation dose is 200 mg/l or highest achievable nominal concentration). General signs and symptoms reported include piloerection, hunched posture, dyspnea, exophthalmos, reduced locomotor activity, tremor, tonic convulsions/spasms and ataxia. No animals died.

II. Other Relevant Information

DOT, EEC, Japanese Classification schemes
EPA Neurotoxicity Testing Guidelines under FIFRA

III. Existing EPA Guidance

EPA has published a number of Q&A's and Status Reports regarding TSCA 8(e). The following Q&As appeared in an EPA document dated July 3, 1989:

Q. What criteria should be used in determining if the results of acute toxicity studies constitute information that reasonably supports a conclusion of substantial risk?

A. Criteria used to determine section 8(e) reporting in the case of acute/subacute findings will depend on the nature of the effects observed and the dose at which the effects occurred. For example, information that shows a tested chemical to be extremely toxic (e.g., causes lethality at very low doses) by, for example, inhalation, dermal application, or oral administration should be reported. On the other hand, the reporting of information showing a chemical to be moderately toxic will depend on the degree of actual or potential exposure to the tested chemical. Information showing a chemical to be slightly or minimally toxic on an acute/subacute basis is not considered typically to be reportable. In addition to extreme toxicity, certain other serious toxicological effects (e.g., neurotoxicity, adverse reproductive system effects) seen in an acute r subacute animal study should be reported und r S cti n 8(e).

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Q. What criteria constitute evidence of reportable neurotoxicity in animal studies? For example, are reversible effects such as narcosis or effects observed in the presence of marked systemic toxicity considered reportable?

A. Typically, neurotoxic effects that are observed in dying animals are not, in and of themselves, considered by EPA to be reportable under Section 8(e) of TSCA. In many cases, however, already reportable data regarding extremely or highly toxic (lethal) substances will be accompanied by information concerning observed neurotoxic effects. In short or long term exposure studies in which serious neurotoxic signs and symptoms (e.g., convulsions, sleep induction, motor dysfunction, narcosis, behavioral dysfunction) are seen in non-moribund animals, however, specific reporting of the neurotoxic effects should take place.

EPA's guidelines also suggest that, while LD50 and other acute screening data may often be outside the scope of section 8(e), there may be circumstances where reporting is required. The following comment appears in 43 Fed. Reg. 11114, March 16, 1978, "Statement of Interpretation and Enforcement Policy":

Comment 14: How are reportable data distinguished from routine tests including range tests such as LD50's.

Response: This policy statement directs the reporting of specified effects when unknown to the Administrator. Many routine tests are based on a knowledge of toxicity associated with a chemical; unknown effects occurring during such a range test may have to be reported if they are those of concern to the Agency and if the information meets the criteria set forth in Parts V and VI.

In reviewing EPA's Status Reports it appears that routine screening tests qualify for reporting only if they demonstrate a significant level of acute toxicity and involve chemicals to which there is significant exposure.

In 1980 (Status Report 8EHG-0479-0282 S, January 9, 1980), EPA explained that its "interest in receipt of acute toxicity studies under Section 8(e) is, in general, fairly limited" but that "under certain circumstances the results of acute studies can provide reasonable support for a conclusion of substantial risk."

"Submitters are expected to consider such factors as the lethal dose, the route of administration, occurrence of unexpected effects in the animals (obtained via "cage side" bservations, during n cropsy, and s n), and the extent

and pattern of the chemical's exposure (insofar as known to the submitter). In general, when evaluating such information under Section 8(e) the greater the acute toxicity of a compound the less heavily one weighs the exposure criteria and vice versa."

In the same Status Report EPA has concluded that acute data demonstrating "extreme dermal lethality" were reportable under Section 8(e) because of the substance's potential for exposure.

In another Status Report, EPA stated that data demonstrating that an R&D chemical was "highly toxic" did not trigger section 8(e) reporting because "acute toxicity data on R&D chemicals which presumably have very limited exposure do not appear to be sufficient to indicate that the material poses a substantial risk to health or the environment." (Status Report 8EHQ-0578-0162 S, June 15, 1978).

Thus, it appears that EPA is uninterested in receiving acute toxicity data under 8(e) unless the effects occur at extremely low doses and involve compounds with significant exposure potential or are associated with more serious, incapacitating effects likely to manifest themselves at a later date.

It should also be noted that in the late 1970's EPA also warned a Chicago based company that they were engaging in "malicious compliance" following the company's submission of large volumes of acute studies under TSCA 8(e). (NOTE: THE GROUP WAS UNABLE TO CITE A REFERENCE - ANYONE FAMILIAR WITH THIS?)

IV. Evaluation Discussion

The study described in Section I should not be submittable under TSCA 8(e) since:

1. the test was a short term study involving a relatively high dose and does not constitute a substantial risk (For example, a 2000 mg/kg oral dose equates to a 40 gram dose for a 20 kg child or 140 gram dose for a 70 kg adult before these effects might be seen).

2. the observations are relatively common signs reported in animals stressed by administering large volumes of test material, as is done in this kind of test. Therefore, they do not reasonably support a conclusion of "serious neurotoxic effects" as outlined by EPA.

3. in limit t sts, if n lethality occurs the material would be classifi d as n n-toxic (at the dos used in this example DOT, OECD and Japan would classify this material

as non-toxic) regardless of the clinical signs and symptoms observed. Thus, EPA would be receiving information that is unlikely to be useful since such signs and symptoms lack significance at large doses.

4. Because of the relatively high dose, the symptoms displayed are generally considered to be reflective of stress on the animal or of "system overload" of the body rather than manifestations of specific toxicological effects due to the particular substance studied.

5. Acute toxicity tests are not sensitive enough or designed to measure neurotoxicity. While signs and symptoms from exposure are recorded, these observations by technicians are visual evaluations. The study design does not generally entail handling or manipulation of the animal to assess the reliability of a subjective visual observation. The EPA, under FIFRA, has established neurotoxicity guidelines that are not addressed by acute toxicity studies. Under these and other guidelines, there are specific tests that are conducted to determine neurotoxicity. These tests typically can include acute neurotoxicity in hens, behavioral testing (mazes, Skinner box), righting reflex, startle reflex, pupillary reflex, hot plate test, etc. The endpoint of acute toxicity testing (limit, LD50) is death. As such, signs and symptoms are gathered to assist the tester in designing additional studies. While the signs and symptoms outlined in this case study cannot be ignored, the relevance to "substantial risk" is not known unless further testing is conducted.

6. If the scenario changed slightly, and some animals died but the signs and symptoms remained the same the study would still not be submittable as it could be interpreted that the animals were moribund (ie: in a dying state) and there would be no way to assess from the information presented which animals died and which recovered.

7. If the route of administration were parenteral (ie: sc, iv, ip) the study would not be submittable as it is not a route of potential exposure in the workplace or general environment. As such, these routes would not qualify as routes of high exposure as outlined in EPA's Q&As.

V. Magnitude of Study Type

Limit tests are commonly conducted tests and observations of non-specific signs of toxicity are commonly observed. If such tests are deemed submittable EPA is likely to receive in excess of one hundred thousand studies for evaluation from all sectors of industry.

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VI. Conclusions

Limit tests in which observations such as lethargy, ataxia and convulsions are recorded are not reportable under TSCA 8(e) since, according to EPA guidance, "information showing a chemical to be slightly or minimally toxic on an acute/subacute basis is not considered typically to be reportable."

CASE STUDY 3

Acute Toxicity —

> 1 Dose —

Neurotoxicity

Human Health Effects Case Study
Acute Toxicity Tests - More than One Dose - "Neurotox"
Draft 3 - April 29, 1991

I. Study Specific Information

The purpose of this case study is to describe the criteria necessary to assess the reportability of acute toxicity tests under TSCA 8(e) that contain various signs and symptoms that might be indicative of neurotoxicity.

An oral LD50 study is conducted in which animals are given 50, 200, 500, 1000 or 2000 mg/kg. Shortly after dosing intermittent lethargy, ataxia and convulsions are described in the 1000 and 2000 mg/kg groups. Salivation, tremors and lethargy are described for animals in the 200 and 500 mg/kg group. No effects were observed at the 50 mg/kg dose group. All rats die at 2000 mg/kg. The rest survive.

II. Other Relevant Information

EPA Neurotoxicity Testing Guidelines under FIFRA.

III. Existing EPA Guidance

EPA has published a number of Q&As and Status Reports regarding TSCA 8(e). The following Q&As appeared in an EPA document dated July 3, 1989:

Q. What criteria should be used in determining if the results of acute toxicity studies constitute information that reasonably supports a conclusion of substantial risk?

A. Criteria used to determine section 8(e) reporting in the case of acute/subacute findings will depend on the nature of the effects observed and the dose at which the effects occurred. For example, information that shows a tested chemical to be extremely toxic (e.g., causes lethality at very low doses) by, for example, inhalation, dermal application, or oral administration should be reported. On the other hand, the reporting of information showing a chemical to be moderately toxic will depend on the degree of actual or potential exposure to the tested chemical. Information showing a chemical to be slightly or minimally toxic on an acute/subacute basis is not considered typically to be reportable. In addition to extreme toxicity, certain other serious toxicological effects (e.g., neurotoxicity, adverse reproductive system effects) seen in an acute or subacute animal study should be reported under Section 8(e).

Q. What criteria constitute evidence of reportable neurotoxicity in animal studies? For example, are

reversible effects such as narcosis or effects observed in the presence of marked systemic toxicity considered reportable?

A. Typically, neurotoxic effects that are observed in dying animals are not, in and of themselves, considered by EPA to be reportable under Section 8(e) of TSCA. In many cases, however, already reportable data regarding extremely or highly toxic (lethal) substances will be accompanied by information concerning observed neurotoxic effects. In short or long term exposure studies in which serious neurotoxic signs and symptoms (e.g., convulsions, sleep induction, motor dysfunction, narcosis, behavioral dysfunction) are seen in non-moribund animals, however, specific reporting of the neurotoxic effects should take place.

EPA's guidelines also suggest that, while LD50 and other acute screening data may often be outside the scope of section 8(e), there may be circumstances where reporting is required. The following comment appears in 43 Fed. Reg. 11114, March 16, 1978, "Statement of Interpretation and Enforcement Policy":

Comment 14: How are reportable data distinguished from routine tests including range tests such as LD50's.

Response: This policy statement directs the reporting of specified effects when unknown to the Administrator. Many routine tests are based on a knowledge of toxicity associated with a chemical; unknown effects occurring during such a range test may have to be reported if they are those of concern to the Agency and if the information meets the criteria set forth in Parts V and VI.

In reviewing EPA's Status Reports it appears that routine screening tests qualify for reporting only if they demonstrate a significant level of acute toxicity and involve chemicals to which there is significant exposure.

In 1980 (Status Report 8EHG-0479-0282 S, January 9, 1980), EPA explained that its "interest in receipt of acute toxicity studies under Section 8(e) is, in general, fairly limited" but that "under certain circumstances the results of acute studies can provide reasonable support for a conclusion of substantial risk."

"Submitters are expected to consider such factors as the lethal dose, the route of administration, occurrence of unexpected effects in the animals (obtained via 'cage side" observations, during necropsy, and so on), and the extent and pattern of th chemical's exp sure (ins far as known to the submitt r). In g neral, wh n valuating such

information under Section 8(e) the greater the acute toxicity of a compound the less heavily one weighs the exposure criteria and vice versa."

In the same Status Report EPA has concluded that acute data demonstrating "extreme dermal lethality" were reportable under Section 8(e) because of the substance's potential for exposure.

In another Status Report, EPA stated that data demonstrating that an R&D chemical was "highly toxic" did not trigger section 8(e) reporting because "acute toxicity data on R&D chemicals which presumably have very limited exposure do not appear to be sufficient to indicate that the material poses a substantial risk to health or the environment." (Status Report 8EHQ-0578-0162 S, June 15, 1978).

Thus, it appears that EPA is uninterested in receiving acute toxicity data under 8(e) unless the effects occur at extremely low doses and involve compounds with significant exposure potential or are associated with more serious, incapacitating effects likely to manifest themselves at a later date.

It should also be noted that in the late 1970's EPA also warned a Chicago based company that they were engaging in "malicious compliance" following the company's submission of large volumes of acute studies under TSCA 8(e). (NOTE: THE GROUP WAS UNABLE TO CITE A REFERENCE - ANYONE FAMILIAR WITH THIS?)

IV. Evaluation Discussion

The study described should not be submitted under TSCA 8(e) since:

1. the observations are relatively common signs of dying animals or from animals stressed by dosing of large volumes of test material in non-emetic species in this kind of test. Therefore, it is not possible to determine whether they reasonably support a conclusion of "serious neurotoxic effects" as outlined by EPA.

2. In this specific example, it is not possible to determine whether one animal or all animals in the dose groups exhibited this effect and whether the observations persisted for the entire length of the study.

3. Acute toxicity tests are not sensitive enough or designed to measure neurotoxicity. While signs and symptoms fr m exp sure are r c rded, these bservations by technicians ar visual valuati ns. Th study design do s

not generally entail handling or manipulation of the animal to assess the raliability of a subjective visual observation. The EPA, under FIFRA, has established neurotoxicity guidelines that are not addressed by acute toxicity studies. Under these and other guidelines, there are specific tests that are conducted to determine neurotoxicity. These tests typically can include acute neurotoxicity in hens, behavioral testing (mazes, Skinner box), righting reflex, startle reflex, pupillary reflex, hot plate test, etc. The endpoint of acute toxicity testing (limit, LD50) is death. As such, signs and symptoms are gathered to assist the tester in designing additional studies. While the signs and symptoms outlined in this case study cannot be ignored, the relevance to "substantial risk" is not known unless further testing is conducted.

4. If the study were conducted as above and the observations stated "convulsions began on day 2 and persisted for the entire length of the study in all surviving animals at the 200, 500 and 1000 mg/kg dose levels" the study would be submittable as it constitutes a "serious neurotoxic effect" as described by EPA. Conversely, if a dose-response relationship was not observed the report would not be submittable.

5. If the study were conducted as above and information were available to indicate that less than four of ten animals per group exhibited convulsions, and the results were seen in one group, the report would not be submittable as the signs and symptoms described are not significant. Conversely, if four or more out of ten animals per group exhibited these symptoms, or dose-related convulsions were noted in several groups in which no deaths occurred, the report would be submittable.

6. If the doses were changed to 10, 25, 100, 1000 mg/kg and convulsions and hind-limb paralysis were observed in a dose-dependant manner the report would be submittable as it would constitute a "serious neurotoxic effect" as described by EPA.

Conversely, if the signs and symptoms reported were salivation, piloerection, lacrimation, ataxia, sleep induction , miosis/ptosis, chromodacyorrhea, decreased or increased movement, or any combination of these, and NO DEATHS OCCURRED, the study would not be submittable as these symptoms are relatively common in acute toxicity studies and it would not be possible to conclude that these effects constitute "serious neurotoxic effects" as described by EPA. However, if deaths occurred and the oral LD50 was reported as less than r qual t 50 mg/kg (d rmal LD50 less than or equal to 200 mg/kg and inhalati n LC50 l ss than or equal to 20 mg/l), th material would b classifi d as extremely toxic and should be r p rt d as it me ts the criteria utlin d by EPA's Q&As and Status Reports.

V. Magnitude of Study Type

Acute toxicity tests are commonly conducted tests and observations of non-specific signs of toxicity are commonly observed. If all tests are deemed submittable without regard to route of exposure or toxic potential EPA is likely to receive in excess of a hundred thousand of these studies for evaluation.

VI. Conclusions

1. In general, acute LD50/LC50 studies in which signs and symptoms that include ataxia, lethargy and narcosis are not reportable under TSCA 8(e) as these are relatively common effects reported in acute studies and their significance cannot be determined without additional testing.

2. Convulsions and/or hind-limb paralysis reported in four of ten animals per group or greater would constitute a reporting obligation as these constitute a "serious neurotoxic effect" as described by EPA.

3. When effects are observed only at the highest dose and no clear dose-response relationship is established the study would not be 8(e) reportable.

4. Other signs and symptoms that might be indicative of neurotoxic effects (eg: salivation, piloerection, lacrimation, ataxia, sleep induction, miosis/ptosis, chromodacyorrhea or any combination of these), are only reportable if the material is extremely toxic (ie: has an oral LD50 of less than or equal to 50 mg/kg; dermal LD50 of less than or equal to 200 mg/kg; inhalation LC50 of less than or equal to 20 mg/l).

CASE STUDY 4

Expected Results

EXPECTED EFFECTS

I. Study Specific Information

A repeat acute oral study (using rats) was conducted on an organophosphorus compound and resulted in an acute oral LD50 value of 2 mg/kg. The first study on this compound, using the same strain of rat, reported an LD50 of 1 mg/kg, and the results were submitted to EPA under TSCA 8(e) based on the high acute toxicity. Clinical signs in both studies included salivation, lacrimation, incontinence of urine and feces, twitching of muscles and decreased physical activity, i.e., typical of the clinical signs expected for this class of chemicals.

II. Other Relevant Information

In light of the chemical class and the results obtained on structurally similar materials, these results were considered typical and expected.

III. Existing EPA Guidance

The definition of "corroborative" needs to be clarified in discussing the issue of reporting "expected" findings. The only formal guidance of "corroborative adverse effects" are contained in the original TSCA 8(e) Interpretation Policy document (March 16, 1978) and suggests that corroborative studies are NOT reportable. The document, however, addresses only published literatur and, furthermore, it does not define

exactly what constitute "corroborative" results. Therefore, it is not clear how to report corroborative results under TSCA 8(e), whether published or not.

IV. Evaluation Discussion

Situation No. 1: Since the first study in the above-mentioned scenario was submitted to the EPA under TSCA 8(e), the conclusion is that the results of the repeat study are NOT reportable. This is because the effects seen were entirely expected, were corroborative with the results of the first study, and were covered under any reporting obligations by the submission of the first study.

Situation No. 2: We now assume the second study was conducted on the original compound, but using a different rat strain. The results are exactly the same as those described previously. With this situation, we conclude that the results of this subsequent study are still NOT reportable for the same reasons, i.e., they were expected, were corroborative with the results of the first study, and were covered by the submission of the first study under TSCA 8(e).

Situation No. 3: We assume that the second study was conducted on the original compound, but mice rather than rats were used. The resulting LD50 value was 12 mg/kg (vs. 1 mg/kg) but the clinical signs were similar. In this situation, despite the different species tested, we concluded that this second report is still NOT reportable because it d es not provide new inf rmation and is less toxic than the riginal rat

results. If the results had been reversed in this example, i.e., the LD50 value for the mouse study was 1 mg/kg vs. 12 mg/kg for the rat study, indicating a higher degree of sensitivity/susceptibility in the second tested specie, the second study results would be considered for possible reporting under TSCA 8(e).

Situation No. 4: We assume that the second study was conducted in the same strain of rats but was administered dermally. The resultant LD50 value was 40 mg/kg (vs. 1 mg/kg orally) but the clinical signs were similar. In this situation, knowledge of the intended/actual uses and potential exposures would need to be considered to determine whether the results warrant reporting as a separate TSCA 8(e) submission.

Situation No. 5: If we use the first scenario again, but now assume that the structure of the chemical in the second test was slightly modified, e.g., the addition of a methyl group, we conclude the results to be non-reportable since this new chemical is from the same class of chemicals, and the results are still typical, and expected, of this class of chemical.

V. Magnitude of Study Type

Results confirming previously observed effects occur frequently. For example, even though a single scenario is used here as an example, it should be recognised that this concept applies to many different toxic endpoints. Other examples include: Irreversible eye damage resulting from compounds having high or low pH values, cancer caused by polycyclic

aromatic hydrocarbons, positive results from the use of positive control compounds, pulmonary sensitization caused by isocyanates, etc.

VI. Conclusion

Results of studies of a corroborative or expected nature for well documented endpoints are NOT reportable under TSCA 8(e) as substantial risk findings. This is because submission of results which corroborate information which the EPA has previously received does not add significantly to the base of new toxicity information, nor does not reporting these expected results within the expedited timeframe of Section 8(e) impede the ability of the EPA to adequately regulate these substances.

VEV-141314

CASE STUDY 5

Eye / Skin Irritation

and

(Animal) Skin Sensitization

Version I

and

Version II

Case Study I. Skin and Eye Irritation and Skin Sensitization

Section I: Study Specific Information

This case study deals with short-term skin and eye irritation studi s and skin sensitization studies in animals.

Section II: Other Relevant Information

Exposure potential, severity, predictability and reversibility of the observed effect, and pH of test substance.

Section III: Existing EPA Guidance

1. The 1978 policy statement and its reporting criteria of "...serious or prolonged incapacitation".

2. Various EPA 8(e) status reports which say skin and eye irritation and corrosion are not reportable. In these reports, EPA elaborated "Submitters are expected to consider such factors as the lethal dose, r ute of administration, occurrence of unexpected effects in the amimals (obtained via 'cage side' observations, during necropsy, and so on), and the extent and pattern of the chemical's exposure (insofar as known to the submitter). In general, when evaluating such information under Section 8(e), the greater the acute toxicity of a compond, the less heavily one weighs the exposure citeria and vice versa."

Section IV: Evaluation Discussion

Th endpoints of skin irritation/corrosion and skin sensitization usually are not substantial risk information. The information is not "any pattern of effects or evidence which resonably supports the conclusion that the chemical substance or mixture can produce canc r, mutation, birth defects, or toxic effects resulting in death, or seri us or prolonged incapacitation." Severe skin effects are not reportable even if wide exposure potential is present unless the effect is unsuspected.

Eye irritation studies which produce reversible eye effects or eye ffects which are irreversible only in the absence of eye washing are not reportable even if wide exposure potential is present. Unless th effect is unsuspected, this information is not reportable because it does not support the conclusion of substantial risk to human health.

Irreversible eye effects may be reportable if coupled with wide exposure potential or if the effect is unsuspected. The factors in Section III.2. sh uld be considered when determining reportability.

Section V: Magnitude of Study Type

Eye and skin irritation studies, and skin sensitivity studies are among the most common type of toxicity testing conducted. Considering mixture testing as well as studies on neat or industrial grad chemicals, these studies have probably been run several times for every chemical that has either been commercialized or to which there has been a potential for worker exposure.

Section VI: Conclusion

Th endpoints of skin irritation/corrosion and skin sensitization usually are not substantial risk information. Severe skin effects ar not reportable even if wide exposure potential is present unless the ffect is unsuspected. Irreversible eye effects may be r portable when considered with other relevant information. Other clinical effects observed in these studies may trigger reporting.

Case Study II. Skin and Eye Irritation and Skin Sensitization

Section I: Study Specific Information

This case study deals with short-term skin and eye irritation studies and skin sensitization studies in animals.

Section II: Other Relevant Information

Exposure potential, severity and predictability of observed effect, and pH of test substance.

Section III: Existing EPA Guidance

1. The 1978 policy statement and its criteria of "...serious or prolonged incapacitation".

2. Various EPA 8(e) status reports which say skin and eye irritation and corrosion are not reportable. In these status reports, EPA considered exposure potential and expected effects of the chemical.

Section IV: Evaluation Discussion

The endpoints of skin and eye irritation/corrosion and skin sensitization studies are not substantial risk information. They ar not "any pattern of effects or evidence which resonably supports the conclusion that the chemical substance or mixture can produce cancer, mutation, birth defects, or toxic effects resulting in death, or serious or prolonged incapacitation." Other clinical observations may trigger reporting especially if the effects observed are unsuspected.

Section V: Magnitude of Study Type

Eye and skin irritation studies, and skin sensitivity studies are among the most common type of toxicity testing conducted. Considering mixture testing as well as studies on neat or industrial grade chemicals, these studies have probably been run several times for every chemical that has either been commercialized or to which there has been a potential for worker exposure.

Section VI: Conclusion

In the absence of other clinical observations which may trigger reporting, information from skin and eye irritation and skin sensitization studies is not reportable.

CASE STUDY 6

SUBCHRONIC TOXICITY

A

TSCA 8(e) CASE STUDY

Subchronic Studies

Section I: Study Specific Information

A subchronic dermal repeat dose study in rats was conducted at doses of 0, 100, 300, and 1,000 mg/kg. The chemical studied is extensively used in consumer products and xposure to the chemical is exclusively dermal. A statistically significant 25% increase in liver weight has observed at the high dose. A statistically significant incidence of clear signs of liver pathology typical of liver cirrhosis was observed at the mid and high doses. The NOAEL is 100 mg/kg. No tumors, effects on reproductive organs or clear indications of neurotoxicity were observed in the study.

Section II: Other Relevant Information

Acute and range finding data on the chemical indicate that it is relatively non-toxic, therefore the high dose chosen for the subchronic study was the OECD recommended limit of 1 g/kg.

Section III: Existing EPA Guidance

Relevant definitions for reportable health studies in the 1978 EPA Guidance Document are in Section IV, paragraphs (a)(1) and (a)(2).

In addition, the July 3, 1989 EPA guidance states the following in regard to serious toxic effects observed in a subchronic study: "includes readily observable serious effects or serious effects seen only as the result of gross and/or histopathological examination. As is the case for acute subacute toxicity studies, the degree of the observed toxicity is important. The more serious (or significant) the observed effect, the less heavily one should consider actual/potential exposure for reporting and vice versa."

Section IV: Evaluation Discussion

The study may be reportable because of the pathological finding directly related to human disease. In order to determine if the study is reportable, the regulatee should consider the magnitude of exposure in the population and the seriousness of the observed effect.

If the exposure to the chemical was expected to be less severe, eg. the uses were industrial or R&D, these findings may not be reportable because the experimental dose levels mployed may not indicate an effect sufficiently serious based on the total exposure potential. This follows EPA guidance which has stated that the degree of toxicity and xposur potential should be considered in determining Secti n 8( ) r portability. In these cases, these r sults may not be r portable unl ss they w re bs rved at doses ne r mor orders f magnitude lower.

If the same results were obtained in an oral study rather than a dermal study, the route of experimental exposure and any information relevant to the actual expected route of exposure (eg. if the expected or actual exposure is dermal, is the chemical substance known or expected to be absorbed through the skin) would also need to be considered before deciding that the study is reportable.

In the event the liver weight findings were observed in the absence of concurrent histopathological findings, the study would not be reportable under most exposure scenarios since there is a strong likelihood that the observations represent only an adaptive respond by the animal to a xenobiotic load. Non-histopathological findings which are observed in isolation, such as body weight effects, organ weight effects, (except reproductive organ effects) changes in a single clinical chemistry parameter, would not constitute a reasonable finding of a serious effect at any dose. Without histopathological findings, multiple observations would need to occur in mechanistically related groups (eg, multiple electrolyte changes indicating renal insufficiency) in order to become "a pattern of effects" which supports a reasonable finding of a serious effect.

In reviewing subchronic studies, the regulatee may be faced with determining whether certain histopathological findings represent true toxicological responses or constitute mere "phenomenology" unique to the test animal species. Controversial examples which exist today are peroxisome formation in the liver and alpha-2-globulin deposition in the kidneys of male rats. The regulatee should gauge the scientific consensus of opinion about the nature of the effect at the time the study needs to be considered for reporting.

Although true histopathological findings alone may indicate a serious effect, some are more serious than others. The regulatee may wish to establish a sliding scale of dosage levels at which various effects are considered serious.

Section V: Magnitude of Study Type

Many large companies have hundreds of subacute or subchronic repeat dose studies. Increases in various organ weights are often seen without concurrent histopathology or functional changes. Criteria are necessary to determine which of the studies indicate a reasonable finding of substantial risk to keep Section 8(e) reporting as useful indicator of unusual, serious findings as opposed to common findings not indicative of substantial risk.

Section VI: Conclusion

Studies where histopathological findings representing serious toxicological events may be reportable. Other factors including dose and actual expected exposure must be examined to determine if the study supports a reasonable finding of a serious effect. Under most circumstances, isolated observations in the absence of concurrent pathology or mechanistically related observations or functional changes, should not be considered for reporting.

CASE STUDY 7

A

'Known To the Administrator'

(Health Effects)

Version I

and

Version II

A

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CIBA-GEIGY

FACSIMILE TRANSMISSION: (202) 887-1237

April 30, 1991

Kathryn A. Rosica
Chemical Manufacturers Association
2501 M Street, NW
Washington, DC 20037

RE.: Case Study(ies) on Health Effects "Known to the Administrator"

Dear Ms. Rosica:

The group felt there was a need to break this into two case studies (attached); one for information learned from government agencies or scientific journals/meetings (Case 1) and another for information previously submitted to either EPA/OTS or EPA/PPO (Case 2).

Some of the points/arguments made in our Case 2 may overlap with the Environmental case study regarding "known to the Administrator."

The blanks for numbers of the various types of submissions in Case 2 (Magnitude of Study Type) need to be filled in yet. I xpect other member companies will be able to estimate these r asonably accurately.

Thanks for your efforts in organizing and directing this fast-track, Herculean task.

Sincerely,

A. Di Battista dch

A. Di Battista
R gulatory Affairs & Toxic Substances Compliance
TRAC

AD04261a.DOC/dch
Attachm nts

A. Di Battista: phone - (914) 479-2776
fax - (914) 478-4839

KNOWN TO THE ADMINISTRATOR - HEALTH EFFECTS

CASE 1

SECTION I: Study Specific Information

A toxicologist in Company A becomes aware of a positive cancer result (or any serious toxicological effect) for chemical X, which it manufactures, via one of the following sources:

a) a phone conversation from a National Toxicology Program (NTP) scientist conducting a bioassay study, which is at the draft report stage;

b) reading a published report in a well-known, peer reviewed, American scientific publication;

c) a presentation at a national Society of Toxicology (SOT) meeting or other widely attended scientific informational meeting.

SECTION II: Other Relevant Information

None

SECTION III/IV: Existing EPA Guidance/Evaluation Discussion

I a) - No specific written guidance is available from EPA regarding obtaining oral information from other government agencies.

EPA is a sister agency of NTP. As a sponsoring or participating Agency, EPA should receive this information in as timely a manner as industry personnel. It can therefore be xpected that the information is known to EPA.

Comment 2. of the 1978 guidance addressed the issue of information reported to other government Agencies, and vice v rsa, as being unduly burdensome and duplicative. EPA's r sponse was essentially that, when coordination with other Agencies is successfully completed, the policy statement will be amended. CMA suggests that, aft r 13 years of TSCA impl m ntati n, th policy statem nt should be amended t not require industry to rep rt studi s that EPA, r s me other federal Agency, is sponsoring or that are publicly available to anyone.

II a) - Section VII c) of EPA's 1978 Policy Statement states that information need not be reported if it has been published in the scientific literature and referenced by the following abstract services ... (six are listed, including NTIS.) Such abstracting, however, would normally occur well past the 15-day deadline. (It could take 3 to 12 months for such abstracts to actually appear in the literature.) CMA suggests that the wording in the 1978 guidance be modified by changing the word "and" to "will be" referenced ... . Alternatively, the wording can be changed to "... scientific journals which are routinely referenced by the following abstracting services... ." This would resolve the 15-day timing dilemma, which cannot otherwise be met, as a practical matter, as the 1978 guidance now reads. If EPA does not wish to actually change or modify the 1978 guidance, the Agency could merely publish a clarification in the Federal Register or the new guidance to the effect that what we are recommending above is what EPA actually means.

Also, EPA should clarify that "reference by the . . . abstracting services" means that it is sufficient that the study be printed in a journal which is routinely abstracted and not that the specific information must also be abstracted.

III c) - EPA toxicologists, as well as industry toxicologists, routinely attend Society of Toxicology meetings and hear the same information at the same time. Additioanlly, they are equally capable of appreciating the significance of such information. We know of no written guidance on this issue. CMA views SOT meetings in the same vein as widely read, well-known scientific publications and recommends that EPA exempt industry from having to separately report such information as being publicly available information.

V - Magnitude of Study Type

There are many credible and well recognized scientific j urnals in the field of toxicology that are (at some point in time) abstracted into one or more of the Abstracting Indices. C llectively, they cover many chemicals and studies. The situations that have been discussed previously, therefore, are quite common and pose a substantial redundant burden on reporting compliance activities, particularly in view of the fact that EPA would ultimately acquir acc ss t th same information.

VI - Conclusion

None of the three examples given above require 8(e) reporting. If reports are required, much duplicative reporting of publicly available information will unnecessarily burden both industry and EPA.

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KNOWN TO THE ADMINISTRATOR - HEALTH EFFECTS

CASE 2

SECTION I: Study Specific Information

Studies or information have previously been submitted to either EPA/OTS or EPA Pesticide Office under:

a) an FYI submission;
b) a Section 4 Test rule;
c) Section 8(d);
d) a PMN;
e) a 5(e) consent order; or
f) a FIFRA registration for R&D pesticides.

SECTION II: Other Relevant Information

None

SECTION III: Existing EPA Guidance

The 1978 policy statement does not specifically address any of the above examples except the straightforward case where significant adverse effects information is obtained on an R&D pesticide after an application for an Experimental Use Permit or FIFRA registration is filed. In such cases, no 8(e) notice is required.

Question 20 of EPA's Q&A summary document following its May 5, 1987 Seminar on Industry Obligations under TSCA addresses the relationship between TSCA Section 8(c) reporting and the reporting of results of studies (1) required to be conducted under Sections 4 or 5 of TSCA, or (2) "listed" under Section 8(d) f TSCA. Essentially, the answer stipulates that "Section 8(e) r porting, in these cases, typically occurs when a Section 8(e) bligation is incurred before reporting of a study is required under Section 4, 5, or 8(d). If other required reporting occurs b fore or coincidental with incurring a Section 8(e) r quirement, the study does not have to be submitted to the 8(e) d cket. The purpose of this exemption is not to change substantially the 8(e) obligation, but merely t avoid r quiring duplicative rep rting, except wh re timeliness consid rations b come paramount."

A

There is no written guidance (to my knowledge) regarding the submission of 8(e) information as FYI.

SECTION IV: Evaluation Discussion

There are at least two separate issues here: a) whether information can be submitted under any of the above authorities in lieu of an 8(e) submission and b) whether information previously (i.e., already) submitted under any of the above examples is "known to the Administrator." The first issue deals primarily with the issue of timeliness while the second one deals with whether "such person has actual knowledge that the Administrator has been adequately informed of such information."

We are concerned in this case study primarily with information that has already been submitted to EPA, particularly for purposes of auditing under the 8(e) CAP program. CMA believes that information that has already been submitted should be x mpt from auditing and 8(e) reporting under the CAP and would fulfill any 8(e) reporting requirements. However, for future reporting purposes, CMA believes that certain types of submissions would not fulfill 8(e) reporting requirements.

a) An FYI submission would not satisfy an 8(e) reporting obligation. It is a voluntary submission and may not b reviewed on a timely enough basis by the Agency receiving it. However, for the purposes of the CAP, we believe any previous FYI submissions submitted to EPA should be viewed as "known to the Administrator" and not be required to be resubmitted under the 8(e) CAP. The issue of timeliness is moot at this point.

b) Information being developed under a Section 4 test rule is patently under the direction and control of EPA. The Agency sets the requirements by rule or consent order agreement of when and how often (interim) results are to be reported. Since the information is being developed in concert with the appropriate EPA office, both the issue of "timeliness" and "known to the Administrator" should be viewed by EPA as requirements that are met in this case. A 15-day deadline should not be required here since the information will be going directly to th EPA office that has responsibility for acting upon the study information.

c) CMA views Health and Safety Studies submitted under mandatory reporting requirements of Section 8(d) as fulfilling 8( ) r porting bligati ns. Since EPA is n t involved in th process, exc pt at the receiving nd, and it ould take up to 60 days from Fed ral Regist r listing f r EPA to get the studies, we believ , in this

case, that requiring a 15-day deadline (and identifying the information as 8(e)) is appropriate. For 8(e) CAP reporting purposes, however, the timeliness issue is moot and any studies previously submitted under Section 8(d) should be viewed by EPA as "known to the Administrator."

d) For PMN submissions, our arguments are similar to those for 8(d) reports. Although all health and safety studies carried out by or known to the submitter are required to be reported with any PMN submission, EPA has no control over when the submission is made and how much earlier the potential 8(e) information was obtained. PMN submissions therefore would not satisfy 8(e) reporting obligations unless the information was submitted timely, i.e., within 15 working days (and identified as potential 8(e) information?) Again, for 8(e) CAP reporting purposes, the timeliness issue is moot and any studies previously submitted in a PMN should be viewed by EPA as "known to the Administrator."

e) Toxicity information developed under a 5(e) consent order is developed with EPA's knowledge and direction. Whatever requirements the consent order stipulates regarding timing and submission of test results should be sufficient for EPA's purposes. A 15-day deadline is unnecessary for reports submitted under 5(e) Consent Orders since EPA is already plugged into the process. Any reports, either in the past or in the future, submitted as a consequence of a 5(e) consent order therefore should be deemed to be "known to the Administrator."

f) TSCA exempts pesticides from the Act and Section 8(e) reporting. R&D pesticides, prior to filing of an Experimental Use Permit or FIFRA Registration, are regulated under TSCA. Because of unclear guidance in the past, certain studies on R&D pesticides may not hav been 8(e) reported. Subsequently, some of these R&D pesticides have been registered under FIFRA and all the studies have been submitted with this registration to EPA's Office of Pesticide Programs. Since EPA now actually has all these reports, the ones carried out while the now registered pesticides were in the R&D stage (and subject to TSCA) should be viewed by EPA/OTS as being "known to the Administrator." Consequently, such studies should not be required to be audited and possibly submitted under the 8(e) CAP. To do otherwise w uld be duplicative r porting and t tally unnec ssary in CMA's vi w.

SECTION V: Magnitude of Study Type

CMA expects there would be a significant number of these types of studies that are already "known to the Administrator." An approximate number of the various types of submissions already mad to EPA is indicated below. It is likely that some 8(e) r p rtable studies would be included among them.

a) _____ FYI Submissions
b) _____ Section 4 Test Rules, _____ studies submitted
c) _____ Section 8(d) chemicals, _____ health and safety studies submitted
d) _____ PMNs
) _____ 5(e) Consent Orders
f) _____ Experimental Use Permits and _____ FIFRA registrations

With respect to R&D pesticides, one major chemical company alone filed several hundred registrations under FIFRA.

By improving internal communications within EPA, a significant burden could be lifted from the Agency and from industry due to limination of duplicate reporting requirements.

SECTION VI: Conclusion

In those areas, such as Section 4 test rules or Consent Order Agreements and 5(e) Consent Orders, where EPA is directly involved in and aware of the type of testing being conducted, the 15-day reporting requirement should be waived. Whatever timing requirements are set by EPA's rule or consent order agreements should suffice. Any studies submitted in these two r as would be deemed to be "known to the Administrator."

In the areas of FYI and PMN submissions, the 15-day reporting r quirement should be maintained for future reporting. For retroactive enforcement and 8(e) CAP reporting purposes, however, such previously reported studies should now be considered to be "known to the Administrator."

Studies on R&D pesticides, which have subsequently been FIFRA registered (or an EUP has been filed), are "known to the Administrator" and do not have to be addressed in the 8(e) CAP.

CASE STUDY B

A

'Serious | Prolonged Incapacitation'

A

CASE STUDY TO EXPLORE THE DETERMINATION OF "SERIOUS OR PROLONGED INCAPACITATION" REGARDING HUMAN HEALTH EFFECTS

Study Specific Information

The Occupational Medicine unit of a manufacturer becomes aware of the following information:

In a manufacturing environment, 18 chemical operators, all working in the same chemical operation were the subjects of medical surveillance including collection of a blood profile.

Notable findings included:

BUN	-	30% above normal (n = 1)
GGT	-	20% above normal (n = 3)
SGOT	-	40% above normal (n = 2)
FEV1	-	marginally (10%) lower than predicted (n = 2)

Depressed proprioception (feet) and vibratory sensation (knee and ankle) - (n = 1)

Other Relevant Information

Several of the chemicals used in the process are on the TSCA inventory. Occupational exposure levels for several are below established acceptable limits. Several of these chemicals are known to produce liver injury to rodents in repeated dose toxicity studies by the oral or inhalation routes, but only at experimental levels far in excess of the occupational standards. None of these chemicals are known to produce human liver or kidney effects. One chemical is a human pulmonary allergen. Employee alcohol and drug intake were reported as negative in the few days prior to the tests. None of the individuals were known to have diabetes. None of the chemicals are known to produce neurotoxicity in humans or animals.

Existing EPA Guidance

The March, 1978 Policy Statement/Guidance Document indicates that information should be reported if "it is possible that effects less serious than those described in Part V(a) may be preliminary manifestations of the more serious effects and, together with another piece of triggering of information."

The following status reports indicate that it is "not completely clear that the information provided...is of the type required for submission...under Section 8(e)," even to the Agency regarding the submission of case studies and medical surveillance data: 8EHQ-0388-06898; 8EHQ-0788-0612; 8EHQ-0888-08228; 8EHQ-0788-0611; 8EHQ-0187-0661.

Further guidance has been given in the 1978 Q & A statements issued by the Agency indicating a dependence upon evidence "strongly implicating one (or a few chemicals)" but without defining "strongly implicating."

Evaluation Discussion

In the specific study described above, there has been no clinical determination of causation regarding any of these findings. Further study of each effect would appear to be warranted before reaching a threshold of reportability.

a) The relatively high BUN level is a single occurrence among a group of similarly exposed workers and there is no previous evidence of renal toxicity associated with any of the process chemicals.

b) The liver enzyme parameters are on the high side of the expected range but still within the norm. Further, the animal toxicity studies provide no reasonable guidance in that liver effects were only seen at very high dose levels with a wide margin of safety to the confirmed occupational levels the workers have been exposed to.

c) The FEV1 values are only marginally decreased and not consistent with past evidence of dose response (i.e., far lower than the NOEL) seen for a human respiratory allergen used in the process.

d) The singular incidence of a neurological disorder is of little diagnostic value without further confirmatory evaluations or correlation to a confirmed human neurotoxin.

Even if one of these "subclinical" findings was determined to be related to chemical exposure, such finding would not be judged, to affect a "serious or prolonged incapacitation" of the employee and thus would need only be listed under section 8(c) and not filed under section 8(e).

Magnitude of the Study Type

Information such as this is not normally considered a true study, but often a case report or surveillance review. It is estimated that literally hundreds of thousands if not millions of such findings are made annually by the U.S. Occupational Health Professionals. Thus, the concept of "preliminary manifestations of the more serious effects" could lead to enormous reporting consequences without clear guidance.

Conclusion

The information of this type is not judged to provide reasonable assurance that a chem(s) can be strongly implicated as to causation and thus are judged not to be reportable under Section 8(e).

Even if determined to be causally related to chemical exposure, we do not believe these effects should reasonably be considered in the context of serious (i.e., loss of organ function) or prolonged incapacitation (i.e., serious impairment) and thus would not require TSCA 8(e) submission.

April 30, 1991

ENVIRONMENTAL CASE STUDIES

VEV-141334

CASE STUDY 9

Extensive/Widespread Contamination

CASE STUDY TO EXPLORE THE DETERMINATION OF "WIDESPREAD DISTRIBUTION IN ENVIRONMENTAL MEDIA"

Study Specific Information

The manufacturer of a volatile liquid chemical substance, which is a known human carcinogen, becomes aware of the following information:

At multiple sites throughout the United States and with various own rships, the chemical substance is stored in storage tanks. All of the tanks are vented to the atmosphere. Emissions into the air have not been measured, but have been calculated using a model. At one of the sites, the owner of a nearby, off-site well monitoring groundwater determines that the well is contaminated with the same chemical substance. However, monitoring wells on the customer's site are not contaminated with the chemical substance. A soil boring sample from the area immediately adjacent to that particular tank shows the presence of the chemical substance at high levels in the soil.

Other Relevant Information

The hydrogeology of the area is not known. Therefore, the manufacturer has not determined that the contamination in the nearby well is due to the same source as the contamination in the soil near the tank. There has been no affect upon the vegetation on any surrounding property not owned by the site-owner. Technology exists to c mpletely remediate the small area of soil contamination. The manufacturer is not aware of similar circumstances at other sites.

Existing EPA Guidance

The March, 1978 Policy Statement/Guidance Document states information must be reported when there is "[w]idespread and previously unsuspected distribution in environmental media, as indicated in studies."

Status Reports indicate that contamination of groundwater and soil is information which EPA believes may be reportable under TSCA § 8(e): 8EHQ-0487-0662, 8EHQ-1088-0759, 8EHQ-1177-0013, 8EHQ-0178-0037. Additionally, in Status Report 8EHQ-1182-0466, EPA states that "releases of less than the reportable quantity of a [chemical substance] should be considered for reporting pursuant to Section 8(e) f TSCA."

The March 1985 issue of Chemicals In Progress, issued by EPA, stated that groundwater is considered a part of the environmental media. EPA restates the 1978 guidance in the July, 1986 Q&A.

Evaluation Discussion

There is no indication of human exposure. Therefore, the information would be reportable only as an environmental effect, if at all. To be reportable as an environmental effect, the manufacturer must consider wh ther the distributi n in the environmental media is "widespread" (provid d other criteria are met).

In determining whether the distribution is "widespread," four criteria should b consider d: 1) Whether the distribution is due to a singl

point source, or multiple point sources which are over a large geographic area; 2) Whether the distribution is manageable (or containable) by known and available technology; 3) Whether the distribution extends beyond the property owned by the manufacturer, distributor or processor considering the information; and 4) Whether the extent of the distribution is known from actual data or is pr dicted/suspected based upon modeling or assumptions.

Here, distribution is described at only one location, although there are multiple potential point sources. Soil contamination is limited to an area immediately adjacent to the storage tank. This soil could be r moved and disposed of using available technology. The air emissions are not known from actual data, but are based upon assumptions and modeling. The contamination in the nearby well has not been shown to be due to the tank; on-site monitoring wells indicate no contamination. This indicates the groundwater has not been affected by the tank and that the distribution is contained within a small area, on the property of the customer. Under these circumstances, the information would not be considered "widespread" for purposes of TSCA § 8(e). The distributions in groundwater and soil appear to be very localized. The distribution in air is unknown b cause actual data do not exist.

The chemical substance here is a known human carcinogen; however, toxicity should be considered only after a determination of "widespread." Thus, this determination as to whether the distribution is widespread would not change if the compound were innocuous. The distribution (or potential distribution) described exists on a site(s) owned by a customer(s) of the manufacturer. However, due to the localized nature of this distribution, the result would not have been different if the distribution had been on property owned by the manufacturer.

Magnitude of Study Type

Information such as this is gathered through monitoring required by various permitting agencies, as well as through self-initiated inv stigations. Examples of common gathering of this information would be the gasoline stations and other underground storage tank facilities around the nation; above-ground tank areas; soil, water and air sampling at manufacturing sites; and landfills ("appropriate disp sal facilities" and otherwise). It is estimated that perhaps mor than 250,000 such bits of information are known in industry. The r porting of this information would result in the dilution of significance for reports under TSCA § 8(e). Further, these matters are managed as required under other statutes regulating air, water, and waste handling.

Conclusion

For the reasons given above, the information of this type does not satisfy the four considerations listed above relevant to determining whether distribution in environmental media is "widespread." Therefore, consideration of oth r criteria for reporting potential environmental eff cts under TSCA § 8(e) are not nec ssary. This Specific Study has not addressed any potential human health considerations.

CASE STUDY 10

'Previously Unsuspected' (Environmental)

A

TSCA 8(e) Compliance Audit Program Case Study

"Previously Unsuspected" Criteria

Assumption:

Whether contamination is "previously unsuspected" will not, of itself, trigger TSCA 8(e) reporting. Other factors (including, for example, a determination that the contamination is "widespread") must also be present to reasonably support a conclusion of "substantial risk" so as to trigger an 8(e) report.

Hypothetical ('Case Study'):

At a 1600 acre plant site used for various industrial purposes over a period of years, soil and groundwater monitoring confirm the presence of an oxygenated organic solvent in an area where this chemical was known by the site owner/operator to have been manufactured (used or stored). Because this contamination is proximately related to the site use-history, the test boring and groundwater results obtained by the owner/operator are not "previously unsuspected" for TSCA 8(e) purposes.

In contrast, monitoring well and soil borings a mile away at the same site confirm the presence of the same oxygenated organic solvent in the site soil and groundwater. The site owner/operator has no reason to believe that the oxygenated organic solvent was manufactured (used or stored) at this other area. Available information does not support a conclusion that the contaminated areas are related, (ie, either resulted from the same spill/release or represent migration of the solvent from one area of the site to the other). Because of this, the confirmed contamination at the second area is "previously unsuspected" for TSCA 8(e) purposes.

Existing EPA guidance

TSCA Section 8(e) does not use the phrase, "previously unsuspected". The 1978 EPA Policy Statement is the origin of this phrase but does not interpret or define it. However, in implementing RCRA, Congress and the EPA presume that industrial properties are contaminated; that contamination will be identified and remedied while the site is still operating. Illustrative of this presumption is the broad range of "corrective action" requirements under RCRA Section 3004(u). CMA believes that whether contamination is "previously unsuspected" under TSCA 8(e) depends on whether the contamination occurs at a location where contamination can be presumed because of chemical usage (site history) or whether contamination occurs in a location where no such presumption can reasonably be made. Factors that should be considered by the site owner/operator include: (1) site history (ie, the manufacture, storage, or use of a particular chemical at a particular site location); (2) knowledge of the contaminating chemicals' migration and/or degradation potential in a particular environmental media; and (3) proximity of newly discovered contamination to an RCI where contamination is found present.

An EPA interpretation of the term "previously unsuspected" which presumes that (current or former) industrial properties are uncontaminated (pristine) or which imposes an "actual knowledge" standard by either the EPA Administrator or EPA-OTS would be an unreasonable and unworkable compliance standard.

WCK: 4/30/91

CASE STUDY 11

'Known to the Administrator'

A

Environmental Case Study - Known to the Administrator

Draft 3 - 4/30/91

Section I: Study Specific Information

This case will focus on information that we feel is "known to the administrator."

A typical U.S industrial site which makes, uses or stores chemicals for disposal will, on a daily basis, be required to comply with a host of state and Federal requirements, many of which require that environmental data/reports will be generated and either retained for inspection or submitted to the governmental agency having primacy. In some cases this will be the EPA (Headquarters od Region); however, in other cases this will be a state or local agency acting under a (a grant of) federal authority. Federal programs that require the generation of data include CWA, FIFRA, RCRA, TSCA, SARA/CERCLA, CAA, Safe Drinking Wat r Act, and Marine Protection Research and Sanctuaries Act. The purpose of such programs is to identify environmental concerns and to take action to remediate them in a timely manner. These programs have their own reporting requirements and enforcement proc dures associated with them. The goals of these other programs are consistent with TSCA section 8(e) in that they are designed so that EPA may receive information enabling it to determine if further action is needed to protect human health and/or the environment. Therefore, there is an overlap in the responsibilities of TSCA 8(e) and these other Federal programs.

Section II: Other Relevant Information

Since the implementation of TSCA 8(e) in 1977, the EPA has dev loped numerous databases and tracking systems that enable the Agency to share data among its federal offices and between the states. Some examples include the Toxic Release Inventory under SARA Title III, IRIS, the Discharge Monitoring Report Inventory under CWA and others.

With the proliferation of environmental laws and regulations, section VII(b)(1) and (2) of the 1978 TSCA 8(e) "statement of interpretation and enforcement policy" (43 FR 11110-16) is now obsolete, duplicative and unnecessary.

Section III: Existing EPA Guidance

The current guidance is outlined in EPA's 1978 TSCA 8(e) "statement of interpretation and enforcement policy, section VII." Included in that document is the following:

"Comment 21: Information exchange systems with oth r Fed ral agencies should b imm diately stablished so that r spondents

A

n ed not report to EPA information already reported to other Agencies, and vice versa. Such duplicative reports are unduly burdensome.

Response: EPA is coordinating this program with other agencies now. When the coordination is successfully c mpleted, the policy statement will be amended to exempt from the reporting requirement information that has been submitted to other specified agencies. In the meantime, substantial-risk information must be reported directly to EPA; such a report does not discharge any reporting obligation to other agencies."

It appears that the amendment of that policy is long overdue.

EPA has, in the past (e.g. March 1985 Chemicals-In Progress Bulletin and EPA Status Report 8EHQ-1182-0466, January 4, 1983), advised reporting companies that submission of information to the Ag ncy under other EPA programs satisfies any TSCA 8(e) notice so that unnecessary duplicative reporting to EPA-OTS is avoided.

[Note: For the sake of brevity, I have removed the detailed discussion from the above cited guidance. They are attached if the group feels that they are needed.]

Section IV: Evaluation Discussion

The following are examples of activities that may generate information reportable under section 8(e) of TSCA but which is pr vided to the EPA under other regulations:

1. Under RCRA corrective action program, facilities are required to investigate spills, leaks, and releases to the environment at their plant. Corrective measures need to be developed, and remediation measures and actions undertaken in a timely manner under RCRA. For example, contaminants from a plant or disposal site have contaminated a drinking water source (e.g. drinking water aquifer or surface water) and concentrations are above acceptable health based levels. Humans may or may not be currently using the water for drinking and other household use. Data are provided to EPA in monthly reports per an approved workplan developed under CERCLA/SARA or RCRA, and as such is typically reported within 30 days of validation.

2. Under NPDES, program reporting can be weekly, monthly, yearly or once every two years depending on the parameter and test. Data are provided directly to EPA in certain states; in NPDES delegated states the data are provided to the state (which administers the program in lieu of EPA).

Using the guidance provided by EPA as outlined above, these data should n t b r p rt d to EPA's Offic of Toxic Substances

under TSCA 8(e). Based on these EPA communications, it is felt that it is the intent of the Agency to minimize duplicative communications and that data already submitted to other Federal agencies in a timely manner should be "known to the Administrator." As such, it should not be necessary to identify these data as TSCA 8( ) nor should it be necessary to submit these data within the 15-day time limit as specified under TSCA 8(e).

Section V: Magnitude of Study Type

The following are estimates of the number of plants and/or sites that generate environmental data which could require audits under CAP:

- 15000 POTWs and 45,000 direct discharges;
- 10,000 RCRA Corrective Actions;
- 1200 Federal CERCLA sites; and unknown number of state "Superfund" sites;
- unknown number of state corrective actions; UST remediations.

There are tens of thousands of reporting opportunities that fall under the auspices of the various EPA sections. The task of reviewing such studies would be enormous, redundant, repetitive, and quite probably counterproductive to the needs of the Agency.

Section VI: Conclusion

In conclusion, environmental studies, reports of accidents, r p rts of spills or releases to the NRC and fish kills that are submitted to other offices or agencies with authority to administer a F d ral program (ie: state agencies and some local POTW's) of the EPA should not be reported to EPA's Office of Toxic Substances und r 8(e) if they are provided in a timely manner as required by other EPA environmental regulations. In addition, submissions to state or local agencies that are either required to be submitted or are voluntarily submitted to the EPA should be exempt from submission under 8(e). Therefore, the requirements specified in secti n VII (b)(1) and (2) of the 1978 TSCA 8(e) "statement of interpretation and enforcement policy" should not apply.

1. EPA March 1985 Chemicals-In-Progress Bulletin

Stated that "information need not be submitted under Section 8(e) if th information has already been reported to EPA pursuant to a mandatory reporting provision of another authority administered by EPA..." The Bulletin does not refer to the need to identify submission under other laws as "Section 8(e) notices" or the need to report within the TSCA 8(e) 15-day time limit.

2. EPA Status Report 8EHQ-1182-0466, January 4, 1983

In describing the relationship between the release notification requirements in Section 103 of CERCLA and section 8(e), EPA noted that emergency incidents of environmental contamination need not be reported under section 8(e) "if the information has already been formally reported to EPA pursuant to mandatory requirements contained in other authorities....". EPA then indicated that "chemical release-related reporting requirements contained in such ther authorities are, for the most part, triggered by incidents involving releases of specified amounts (i.e., reportable quantities (RQs) of specific (i.e., listed chemical substances)). In those cases involving a release of less than a reportable quantity of a listed chemical or a release of a chemical not listed in such other authorities, companies should consider the need for reporting pursuant to section 8(e) of TSCA. EPA concluded that secti n 8(e) notification was unnecessary because, "(1) the duPont chl rine gas release involved a release of a reportable quantity of a listed chemical substance, and (2) the incident was immediately reported by the company to EPA pursuant to the notification provisions of CERCLA.

CASE STUDY 12

Exposure / Numerical
Cut offs
(Environmental)

I. *Study Specific Information*

The purpose of this case history development is to describe the criteria necessary to assess the reportability of environmental effects under 8(e).

II. *Case Study*

Q: Companies conduct routine environmental toxicity studies (i.e., aquatic) typically run for product hazard evaluation. These studies only represent the toxicity of the product and not use or exposure patterns. These studies can at best represent hazard if spilled during transport. These studies do not include information on the degradation, half-life, or chemical reaction potential. Similarly, end of pipe environmental bioassays are run for compliance with state permitting programs.

A: Environmental toxicity studies alone do not qualify as an 8(e) report. As EPA said in its 1978 Statement of Interpretation, exposure is the other necessary consideration. End of pipe bioassays like industrial hygiene monitoring only demonstrate compliance with permit regulations and is not reportable.

Q: A Substance "X" is found at trace levels exclusively in the soil or ground water of the facility. After further evaluation, it is later detected at trace levels downstream from the facility. This stream feeds a larger waterway. The toxicity of Substance "X" is unknown, but toxicity data is available for a similar substance which has an established federal water quality criteria. Substance "X" in the waterway is detected at levels below the federal water quality criteria for the similar substance. The similar compound is highly toxic. Substance "X" does not bioaccumulate or there is no data to confirm bioaccumulation and no non-trivial adverse effects are recognized to any flora or fauna in the stream containing the compound.

A: This is not a substantial risk notice since the evaluation of both the toxicity and exposure demonstrate no substantial risk. If Substance "X" is toxic at levels found in the waterway *and* the substance bioaccumulates and/or causes non-trivial adverse effects to flora or fauna, reporting would be required.

Q: A compound containing a known animal carcinogen is released into a public drinking water source, its presence is detected in surface water beyond your operating site. Its detection level is above the acceptable federal levels set for drinking water.

A: Since this compound would demonstrate potential human risk, reporting under 8(e) would be required. If the level detected in the drinking water source is below the acceptable federal levels set for drinking water standards, then reporting is not required.

III. *Existing EPA Guidance*

In EPA's 1978 Policy Statement Part V (b) environmental effects of any non-trivial adverse effect, previously unknown to the Administrator, known to have a pronounced bioaccumulation and to be widespread and previously unsuspected distribution in environmental media, or (c) emergency incidents of environmental contamination require notice to the Administrator. EPA states that environmental effects must also involve the potential for significant levels of exposure.

It is clear that environmental effects alone or a compounds presence does not require reporting under 8(e). The environmental effects and exposure must both be considered.

V. *Magnitude of Study Type*

Thousands of environmental effect studies are conducted yearly. This information itself does not assess environmental exposure as required in the 1978 Statement of Interpretation, and assessment of environmental effects is futile without evaluation of exposures.

VI. *Conclusion*

Toxicity data or the presence of a compound in environmental media is insufficient to warrant 8(e) reporting. The degree of exposure and effect to environmental species must be evaluated and both must be present to require reporting. If the exposure from contamination causes serious threat to humans, then reporting is required.

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JJK004.33 Rev. 4-30-91

Recommendations to ammend 2nd Draft from J. Kaspa

1 - Drop the phrase "Trace Levels" from the first and second sentences of Q2.

2 - Modify second sentance in A2 To read: "....
... waterway and the substance shows pronounced bioaccumulation and/or discovered to have an n-octanol/water partition coefficient of greater than 25,000 and the substance causes non-trivial.....".

III - Existing EPA Guidance
Add the following.

USEPA Statement of Interpretation published on March 16, 1978 defines pronounced bioaccumulation to mean bioaccumulation in fish beyond 5,000 times water concentration in a 30-day exposure or having an n-octanol/water partition coefficient greater than 25,000. It further indicates that pronounced bioaccumulation is reportable only when coupled with potential for widespread exposure and any non-trivial adverse effect.

Comments from D.TOH/ Eastmen

I. *Study Specific Information*

The purpose of this case history development is to describe the criteria necessary to assess the reportability of environmental effects under 8(e).

II. *Case Study*

Q: Companies conduct routine environmental toxicity studies (i.e., aquatic) typically run for product hazard evaluation. These studies only represent the toxicity of the product and not use or exposure patterns. These studies can at best represent hazard if spilled during transport. These studies do not include information on the degradation, half-life, or chemical reaction potential. Similarly, end of pipe environmental bioassays are run for compliance with state permitting programs.

estimate potential

or mammalian toxicity

the chemical is

A: Environmental toxicity studies alone do not qualify as an 8(e) report. As EPA said in its 1978 Statement of Interpretation, exposure is the other necessary consideration. End of pipe bioassays, like industrial hygiene monitoring, only demonstrate compliance with permit regulations and is not reportable.

Q: A Substance "X" is found at trace levels exclusively in the soil or ground water of the facility. After further evaluation, it is later detected at trace levels ~~downstream from~~ outside of the facility. This stream feeds a larger waterway. The toxicity of Substance "X" is unknown, but toxicity data is available for a similar substance which has an established federal water quality criteria. Substance "X" in the waterway is detected at levels below the federal water quality criteria for the similar substance. The similar compound is highly toxic. Substance "X" does not bioaccumulate or there is no data to confirm bioaccumulation and no non-trivial adverse effects are recognized to any flora or fauna in the stream containing the compound.

A: This is not a substantial risk notice since the evaluation of both the toxicity and exposure demonstrate no substantial risk. If Substance "X" is toxic at levels found in the waterway *and* the substance bioaccumulates and/or causes non-trivial adverse effects to flora or fauna, reporting would be required.

Q: A compound containing a known animal carcinogen is released into a public drinking water source, its presence is detected in surface water beyond your operating site. Its detection level is above the acceptable federal levels set for drinking water.

A: Since this compound would demonstrate potential human risk, reporting under 8(e) would be required. If the level detected in the drinking water source is below the acceptable federal levels set for drinking water standards, then reporting is not required.

VEV-141350

Q: A known human carcinogen is found on in ground water at an operating site. Analysis of groundwater at the facility shows no migration of the chemical off site.

~~at~~ such > ~~above~~ the drinking H2O standard

A: Since there is no ~~exposure~~ documented exposure to a susceptible

A

III. Existing EPA Guidance

In EPA's 1978 Policy Statement Part V (b) environmental effects of any non-trivial adverse effect, previously unknown to the Administrator, known to have a pronounced bioaccumulation and to be widespread and previously unsuspected distribution in environmental media, or (c) emergency incidents of environmental contamination require notice to the Administrator. EPA states that environmental effects must also involve the potential for significant levels of exposure.

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VI. Conclusion

alone

Toxicity data or the presence of a compound in environmental media is insufficient to warrant 8(e) reporting. The degree of exposure and effect to environmental species must be evaluated and both must be present to require reporting. If the exposure from contamination causes serious threat to humans, then reporting is required.

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VEV-141351

Environmental

Case Study

13 & 14

Miscellaneous

Submitted FYI

A

Proposition 65 (Water Case Study)

Section I. Study Specific Information

Proposition 65 is a California law that requires that individuals be warned prior to being exposed to carcinogens or reproductive toxins above the "no significant risk level (NSR)."

Proposition 65 also prohibits the discharge of any listed carcinogen or reproductive toxin in an amount above the NSR to any drinking water or source of drinking water. The NSR level has been established as one in 100,000 for carcinogens and 1/1000 of the No Observable Effect Level (NOEL) for reproductive toxins.

Air dispersion modelling using the standard ISCST model of these air emissions predicts ground level concentration at specific distances radiating from the emission source. The air c ncentrations of chemicals are converted to cancer risk by multiplying the air concentrations by the unit cancer risk factor established for the carcinogen by EPA or the California Department of Health Services. For some chemicals which are emitted as particulates, multipathway risk assessment must also be conducted because these particulates will eventually be deposited on land, a water body, or a "source of drinking water." Guidance from EPA is requested regarding the modelling of these particulates which fall on "sources of drinking water."

Section II. Other Relevant Information

Virtually all the land and all the waters in the state of California, with exception of the Salton Sea and the Pacific Ocean, have been defined as "sources of drinking water." This has resulted in reports which describe the potential contamination of a dry creek bed (in many cases, dry for this century) or flood control plain as contamination of "drinking water sources". There are no provisions in California regulations dealing with whether or n t a "drinking water source" could actually be used for drinking water.

For several carcinogens, i.e. benzene, hexavalent chromium, and methylene chloride, the unit risk factors are approximately 10 fold higher in California than in other states which use the EPA unit risk factors. In addition, the NSR level for thoroughly d cumented reproductive toxins (such as lead) is 1/1000 of the NOEL. This risk level is 10 times lower than the 1/1000 of the NOEL which is commonly used in developing a variety of reference standards . For instance, the drinking water standards are in the ppm range but the no significant risk levels under Prop sition 65 are in the ppb range. The impact of these m re stringent standards in Calif rnia is that when one tries t evaluate "substantial risk

t health" one finds that more risks are significant risks in California than they would be if the same level of carcinogen or reproductive toxins contamination were found in other states.

Section III. Existing EPA Guidance

None

Section IV. Evaluation Discussion

If the carcinogenic unit risk factors and no significant risk levels for reproductive toxins developed by California agencies are used to established risk, there will be more cases of risk in California than in other states with the same level of c ntamination. California industry will be making more submissions to the EPA than would be required from other states. More importantly, these submissions will create "substantial" risks from risks which are not substantial. EPA should indicate that EPA carcinogenic risk factors and other reference standards should be used to maintain a "level playing field" within the states and with regard to the substantial risk information that EPA must assimilate, analyze and prioritize. The level of risk that EPA c nsiders "substantial" should also be established by EPA.

EPA should also indicate that only legitimate bodies of water that are used as sources of drinking water, or for fishing need be considered for the 8(e) notification.

Section V. Magnitude of Study Type

Every quarter, more chemicals are added to the Proposition 65 list of chemicals. Some companies will be conducting a risk assessment that frequently in order to determine if their discharges are in compliance or their air emissions are in compliance.

AB2588 (Air Emissions Case Study)

Section I. Study Specific Information

California law AB2588 requires that businesses quantify and c nduct health risk assessments on approximately 300 chemicals on the AB2588 list. The list contains carcinogens, non-carcinogens, and acutely toxic chemicals. Chemicals with emissions above a threshold quantity, which ranges from 0.1 lbs/year to 100 lbs/year, must have a health risk assessment performed. Modelling of these emissions are used to predict ground level concentrations at specific distances radiating from the emission sources. The air concentrations of chemicals are converted to cancer risk by multiplying the air concentration by the unit cancer risk factors stablished for the carcinogen by EPA or the California Department of Health Services. For some chemicals, multipathway analysis is required in the risk assessment.

The cancer risk from emissions from the facility is the sum of the individual cancer risks of all chemicals emitted from all sources at the facility. The individual excess cancer risk is determined for the maximum exposed individual. The total excess lifetime cancer risk is also determined for the worker and residential population within the one-in-a-million-risk zone surrounding the facility. The total population excess cancer burden is calculated as the product of the exposed population and th estimated risk from the ambient air concentration.

The risk assessment must also include an evaluation of the potential non-cancer effects of both short term and long term exp sures to facility emission. The short term and long term exp sure levels are compared to acceptable exposure levels determined by the California Department of Health Services. Adverse health effects are assumed to occur when the acceptable exposure levels are exceeded. In cases where multiple chemicals can affect the same target organ, the hazard index approach is used. The estimated exposure to a given substance is divided by th acceptable exposure level for that substance. For a given target organ, this ratio (the hazard index) is summed for all substances which affect that target organ. If the hazard index equals or exceeds 1.0, a potential health hazard is assumed to exit.

Based on these risk assessments, facilities with a cumulative cancer risk and a cumulative hazard index that exceed certain thresholds established by the local Air Pollution Control Districts will have t n tify the public of the risks.

Guidance is requested from EPA regarding interpretation of "significant levels of exposure," "widespread", and "previously unsuspected" contamination.

Section II. Other Relevant Information

The poor quality of the air in Los Angeles is both well known and well documented. In 1987, the South Coast Air Quality Management District (SCAQMD) published a study on the magnitude of the ambient air toxics impacts in the air basin. This study was funded under EPA's Multiple Air Toxics Exposure Study Program (MATES), and the study results have been submitted to the EPA under the Clean Air Act. The study integrates ambient concentration, population distribution, and health risk data into regional estimates of inhalation exposure, risk, and number of excess cancer cases.

The AB2588 risk assessments provide exposure and risk information that is similar to what is contained in the SCAQMD document. However, the AB2588 risk assessments indicate that a given business is responsible for a part of the widespread contamination of the air in the Los Angeles area. Although the wid spread contamination is previously known to EPA (via submission of documents under Clean Air Act) what may not have been known (and documented) previously, is which businesses contributed to the air t xics and the extent of their individual contribution. In the instances for which permits were required, the SCAQMD is knowledgeable of the businesses involved as well as type and quantity of emissions. In the instances for which permits have not been required, the SCAQMD would not have direct knowledge of business and emissions. If the SCAQMD does not have direct knowledge, it might be argued that the information presented in the risk assessment involves "previously unsuspected" contamination.

For several carcinogens, i.e., benzene, hexavalent chromium, and methylene chloride, the unit risk factors are approximately 10 f ld higher in California than in other states which use the EPA unit risk factors. In addition, for this regulation, hexavalent chromium is carcinogenic by the ingestion route, which tends to cause hexavalent chromium to dominate the risk assessment for certain industries. The impact of applying these more stringent r gulations is that when one tries to evaluate "substantial risks t health" one finds that more risks are substantial risks in California than they would be if the same level of carcinogenic c ntamination were postulated in other states.

Section III. Existing EPA Guidance

None

Section IV. Evaluation Discussi n

If the carcinogenic unit risk factors developed by California Agencies are used to establish risk, there will be more cases of "substantial risk to health" in California than in other states with the same levels of contamination. California businesses will be making more submissions to the EPA than would be required from other states. More importantly, these submissions will create substantial risks from risks which are not substantial. EPA should indicate that EPA carcinogenic risk factors and other EPA reference standards should be used to maintain a "level playing field" within the states and with regard to the substantial risk information that EPA must assimilate, analyze and prioritze.

The level of risk for carcinogens and the reference standards for non-carcinogens (eg, RFD, TLV/420) that EPA considers "substantial" should also be established by EPA.

Interpretation of "widespread" contamination should focus on th differentiation (if any) between a large geographical area and a large population that is exposed. For instance, the SCAQMD r gulations affect 5 counties, some of which are heavily populated, and some of which are primarily vast expanses of sparsely populated desert. If one must consider "widespread" in conjunction with "substantial risk to health", additional guidance is needed. For example, if the residents within a radius of one quarter mile of a facility are at a risk of 10 (-4), are the "widespread" and "substantial risk" criteria satisfied? If 1 million persons within th 25-30 mile radius of a facility are at a risk of 10 (-6), are the "widespread" and "substantial risk" criteria satisfied?

If one is lucky enough to have documentation, such as the 1987 SCAQMD study conducted for MATES, of concentrations of chemicals in environmental media, how should one compare those concentrations with the concentrations in a risk assessment such as AB2588? It s ems reasonable to come to the judgement that in situations in which the environmental concentrations predicted from a risk assessment do not exceed the concentration documented (as in a MATES study) by some factor (such as by a factor of 2 which is the accuracy of a Gaussian-derived model such as the ISCST model), that the criteria for "previously unsuspected" contamination have not been met, and the risk assessment results would, therefore, not be required to be submitted under 8(e).

Section V. Magnitude of Study Type

The AB2588 risk assessments will be required every two years.