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RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

August 1, 2013

Ms. Heather White
Executive Director
Environmental Working Group
1436 U Street, N.W.
Suite 100
Washington, D.C. 20009

Dear Ms. White:

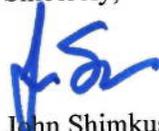
Thank you for providing testimony to the Subcommittee on Environment and the Economy on Friday, July 11, 2013, hearing entitled "Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Thursday, August 15, 2013. Your responses should be e-mailed to the Legislative Clerk in Word format at Nick.Abraham@mail.house.gov and mailed to Nick Abraham, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



John Shimkus
Chairman

Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy

Attachments

The Honorable John Shimkus

1. You make a number of recommendations about changes to the TSCA program.
 - a. How many of them does EPA already have authority to do?
 - b. How many of those remaining from your list could be done administratively versus via statute?
2. You state that in contrast to an EPA employee, “a company faces little risk if it abuses confidential business information provisions under TSCA.”
 - a. Does this mean you would support penalties for anyone who abuses CBI, including Third Parties that publish CBI claimed materials?
3. Your testimony, by noting TSCA gives EPA just 90 days to review a Pre-manufacture Notice (PMN) for a substance before it goes on the market, implied this leads to poor decision making by EPA. It's my understanding that the regulatory procedures that accompany this provision require EPA to merely *take* action within 90 days, but those actions include options such as requesting an extension or even rejecting the PMN. As a result, the time it takes for final EPA approval can often be much longer than 90 days -- and, in fact, may even be years (during which period of time the product cannot be placed on the market). What is your understanding of, or experience with, the PMN review period, especially for substances that fall into EPA categories of concern?
4. Your statement made several assertions about the lack of testing of chemicals under TSCA's new chemicals program, including that:
 - a. EPA faces a Catch-22 when it comes to new chemicals. The agency cannot request additional data unless it has safety concerns and it cannot adequately address safety concerns without relevant testing data.
 - b. EPA, with no test data to evaluate the safety of a new chemical, must use computer models, incomplete chemical comparisons and other analyses to predict how it may affect human health and the environment.
 - c. EPA models and estimates are based on data about previously studied chemicals, not necessarily how a new chemical will behave.”

Based on this testimony:

- i. Do you acknowledge that EPA can and does indirectly require companies to test new chemicals under its PMN program?
- ii. Do you dispute that EPA's evergreen guidance/Q & As/website on its new chemicals program, for example, make clear that EPA can decide not to approve a PMN without more data/information or to approve a PMN but regulate it stringently on the basis of default assumptions in the absence of data? See: <http://www.epa.gov/oppt/newchems/pubs/qanda-newchems.pdf> and <http://www.epa.gov/opptintr/newchems/pubs/possible.htm>
- iii. Please explain the intersection of your statement with the provisions of TSCA Section 5(e), authority which allows EPA to impose testing requirements on new chemicals after they are first introduced into commerce?

5. Please explain why and how you differ with the perspectives of former EPA officials¹, who have noted the scientifically robust nature of predictive analyses -- such as SAR, read-across, PBT profilers -- for determining whether a new chemical may present an unreasonable risk?
6. Your testimony claims that when health and safety data are restricted from disclosure the public pays. However, section 14 specifically provides that EPA “shall disclose [CBI] if the Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment”?
 - a. Do you dispute that such a provision exists in TSCA section 14(a)(3)?
 - b. Do you dispute that data from health and safety studies are not protected from release under TSCA section 14(b)?
7. Your testimony asserts that 95% of all pre-manufacture notices (PMNs) for new chemicals contain information manufacturers have designated as confidential.
 - a. Since EPA is the regulator, has the CBI and can review it, and the PMN substances are not in commerce, what is the relevance of this statistic to your testimony?
 - b. Doesn't EPA have the authority not to approve the PMN if the agency is concerned about the potential health or environmental effects of a PMN confidential substance?
 - c. Can't the agency also approve the PMN but issue a significant new use rule (SNUR) on the chemical if it wants to review the substance again before it is used in any other new application?
8. Your testimony applauds EPA for its recent efforts to audit and declassify claims of confidential chemical identity in approximately 900 health and safety studies. As I understand it, EPA's CBI Declassification Challenge to industry actually determined that 11,553 (almost 75%) of 15,752 cases believed to contain CBI, after review, were shown to not contain any CBI at all.
 - a. Do you dispute that 11,553 of 15,752 cases were found not to contain any CBI?
 - b. Does this statistic alter your perception about alleged industry abuses of CBI? If not, why not?

The Honorable Henry A. Waxman

When this Committee began working on TSCA reform four years ago, several groups offered principles for TSCA reform. These principles included broad support for the idea that manufacturers should prove that the chemicals they produce and sell in the United States are not putting consumers, workers, hot spot

¹See the testimony and the annex within it presented by Charles Auer at this subcommittee's June 13 hearing on TSCA, found here: <http://energycommerce.house.gov/hearing/title-i-toxic-substance-control-act-understanding-its-history-and-reviewing-its-impact>. Also see American Bar Association article on TSCA, authored by four former EPA officials and its discussion of the new chemicals program, attached here. http://www.epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=86806f67-e47e-4cf3-9612-550104e7685a

communities, or vulnerable populations at risk. The principles also included broad support for reducing overclaiming of confidentiality and promoting greater transparency regarding chemical risks.

1. Does the Environmental Working Group still support placing the burden on manufacturers to demonstrate that their products do not pose risks to consumers, workers, hot spot communities, and vulnerable populations?
2. Does the Environmental Working Group still support reducing overclaiming of confidentiality and promoting transparency?
3. Should those important principles be included in any effort to reform TSCA?
4. What other reforms are essential to include in TSCA reform if the statute is to be made effective and protective for everyone, including vulnerable populations?
5. Are those reforms included in the bill recently introduced in the Senate to reform TSCA?
6. Does the Environmental Working Group have concerns about that bill?

At the July 11, 2013, hearing, industry witnesses testified that current disclosures, including structurally descriptive, generic chemical names are sufficient for consumers.

7. Do you agree with that statement?

Much of what is known about chemical risk under the existing TSCA scheme is submitted to EPA and published online in the form of TSCA §8(e) notices. Several examples of such notices are attached. These examples, from the most recent batch posted for the public by EPA, have been redacted to protect information claimed by the submitter as confidential business information (CBI). The redactions include information that a consumer might use to identify the chemical implicated.

Almost the only thing left unredacted is the description of the harms found through chemical testing - "erosions and ulcerations in the forestomach," "severely dysfunctional pathological changes," and "spontaneous death." Clearly, these are chemicals that consumers could reasonably choose to avoid.

8. Do these redacted notices provide enough information for consumers to make informed choices and avoid these chemicals if they so desire?

One of these notices also provides an example of what a manufacturer views as substantiation of a CBI claim. The manufacturer writes, "Disclosure of this information would harm [REDACTED]'s efforts to commercialize this compound." Given the serious risks identified in the notice, including atrophy of reproductive organs, it seems quite likely that disclosure of this risk information could harm efforts to commercialize this compound.

9. Like many in the public interest community, the Environmental Working Group has sought up front substantiation of confidentiality claims. In your view, should a substantiation like this be sufficient?

353368

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OPPT CBIC

2013 APR 11 AM 6:00



April 3, 2013

This Report CONTAINS Confidential Business Information

DELIVERY BY CERTIFIED MAIL
CONFIRMATION OF RECEIPT REQUESTED

Document Control Office (7407M)
U.S. Environmental Protection Agency
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001



SUBJECT: TSCA 8(e) SUBMISSION

Dear Sir or Madam:

() (formerly) is submitting certain data which we believe to be reportable under TSCA 8(e). The information concerns , an experimental aryl hydrazide insecticide. is identified by IUPAC as:

The CAS number assigned for this compound is

recently learned of new toxicological effects in a one month oral toxicity study of in rats. An outline of the study follows:

One month oral toxicity study of in rats

was administered daily in feed to male and female rats at dose levels of 10, 100, 300, and 1000 ppm for one month. The No Observed Adverse Effect Level (NOAEL) was 10 ppm for both sexes (male rats: 1.1 mg/kg/day, female rats: 1.0 mg/kg/day). In addition, severely dysfunctional pathological changes, such as atrophy of prostate, seminal vesicle, vagina (epithelium), uterus, and thymus were observed.

believes that the NOAEL of <200 mg/kg/day in an oral study of \leq 4 weeks, and the pathological changes are reportable under TSCA 8(e).

Performing Laboratory:

Study methods:

Test substance:

Animals: Br/Han:WIST@Jcl(GALAS) rats, males and females, 6 animals/sex/group

Animal age at initiation of treatment: 5 weeks old

Body weight range at initiation of treatment: males: 107 to 118 g; females; 90 to 107 g

Administration route: Oral via diet

Dose levels: 10, 100, 300, and 1000 ppm

Treatment period: one month

Observation items: Clinical signs, body weight, food consumption, ophthalmology, urinalysis, motor activity, FOB, hematology, blood biochemistry, gross pathology, organ weight, histopathology, electron microscopic examination

RESULTS:

Low body weight and/or suppressed food consumption were observed in both male and female rats at 300 and 1000 ppm. As a result of hematology, blood biochemistry, gross pathology, organ weight or histopathology, some changes indicating hemolytic anemia were observed in both sexes at 100 ppm and above, and the effects on liver were observed in both sexes at 300 and 1000 ppm.

Substantiation of CBI Claims

We wish to substantiate 's claims that certain information in this letter be treated as Confidential Business Information ('CBI'). All information which has been deleted from the sanitized version of this letter (copy attached) should be treated as CBI. In substantiation of this CBI claim, wishes to protect its confidential business plan for the commercial development of this compound. Disclosure of this information would harm 's efforts to commercialize this compound. Please refer to the attached letter regarding substantiation of CBI claims.

If there are any questions on this submission please feel free to contact me at ().

Sincerely,

meth
342508

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OPPT CBIC

2012 MAR -9 AM 10:40

Sanitized Copy

March 8, 2012



Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e)
Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: 8EHQ-12-18571 [Supplemental Information]
Notice in Accordance with Section 8(e): Results of OECD 422 Combined Repeated
Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in
Wistar Rats with [REDACTED]
[REDACTED] CAS No. [REDACTED]

Dear Sir/Madam:

We are submitting supplemental information related to our initial submission dated
February 21, 2012 [8EHQ-12-18571]. This information was inadvertently omitted due to a clerical
error; therefore, we are submitting a corrected version of the Confidential Letter and the Sanitized
Letter.

[REDACTED] is submitting results of OECD 422 Combined Repeated Dose Toxicity Study
with the Reproduction/Developmental Toxicity Screening Test in Wistar Rats [Cr:WI(HAN)] with
[REDACTED] CAS No. [REDACTED], conducted by [REDACTED].

The aim of this study was to obtain initial information on the possible effects of the substance on the
integrity and performance of the male and female reproductive systems including gonadal function,
mating behavior, conception, gestation and parturition. Furthermore, information about the general
toxicological profile including target organs and no-observed-adverse-effect-level (NOAEL) should
be elucidated.

The study was carried out with reference to the requirements of the following guidelines:

- OECD Guidelines for Testing of Chemicals; No. 422, Combined Repeated Dose Toxicity
Study with the Reproduction/Developmental Toxicity Screening Test (22 Mar 1996)
- EPA, Health Effects Test Guidelines; OPPTS 870.3650: Combined Repeated Dose Toxicity
Study with the Reproduction/Developmental Toxicity Screening Test (Jul 2000)



Company Sanitized

Sanitized Copy

United States Environmental Protection Agency - East
March 8, 2012
Page 2

The test substance was administered by gavage at dose levels of 0; 100, 300 and 1000 mg/kg bw/d. Because premature deaths in animals of test group 3 (high dose), the dose level for this group was reduced from 1000 to 600 mg/kg bw/d during the mating period (study day 19).

All animals were observed daily for any clinical signs during the study period.

After a 14-day pre-mating period, the male and female parental animals were mated overnight in a 1:1 ratio until evidence of copulation (vaginal smear). The day on which sperm was detected was referred to as gestation day (GD) 0 and the following day as GD 1. All parental males were sacrificed and examined after the end of the administration period (at least 28 days). The parental females were allowed to deliver and rear their pups until postnatal day (PND) 4. On PND 4, all pups were sacrificed and examined.

The following is a summary of the most relevant results:

Test group 3 (1000 and 600 mg/kg bw/d):

Males:

- One male animal was found dead on study day 35.
- Salivation after treatment in all animals over the entire study period.
- Erosions and ulcerations in the forestomach of all male animals

Dams:

- One female animal was found dead on study day 16 (mating day 3) and another one was sacrificed moribund on study day 18 (gestation day 2).
- Salivation after treatment in 9 of 10 animals over the entire study period.
- Piloerection after treatment was observed in 3 female animals during gestation and lactation periods.
- Hunched posture was observed in 1 female during gestation.
- Semiclosed eyelids after treatment were observed in both eyes of 2 animals during gestation.
- Respiratory sounds were observed in 3 females during gestation.
- Two animals were gasping during gestation.
- One animal showed vaginal discharge during gestation.
- Poor general condition in 2 animals during gestation.
- Erosions and ulcerations in the forestomach of 9 of 10 female animals
- Postimplantation loss of 19%

Sanitized Copy

United States Environmental Protection Agency - East
March 8, 2012
Page 3

Test group 2 (300 mg/kg bw/d):

Males:

- Salivation after treatment in 9 of 10 animals over the entire study period.
- Piloerection after treatment was observed in 1 male animal on study day 23.
- Erosions and ulcerations in the forestomach of 3 of 10 male animals.

Dams:

- Salivation after treatment in 5 of 10 animals over the entire study period.
- Erosions and ulcerations in the forestomach of 5 of 10 female animals

Test group 1 (100 mg/kg bw/d):

Males:

- Salivation after treatment in 2 of 10 animals over towards the end of the treatment period.

Dams:

- One animal, with only one implantation site, delivered one dead pup

The latter effect is assessed as being incidental, as such findings are occasionally noted in control animals, and were not observed at 300 mg/kg bw/d.

[XXXXXXXXXX] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

Sincerely,

Enclosures

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2013 JAN -4 AM 10:40

MR# 350894

Sanitized Copy

January 3, 2013

Via Federal Express



United States Environmental Protection Agency - East
Attn: TSCA Section 8(e) / Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: Notice in Accordance with TSCA Section 8(e): Results of a combined repeat dose reproduction toxicity screening test with [REDACTED]

Dear Section 8(e) Coordinator:

[REDACTED] is submitting results of a combined repeat dose reproduction toxicity screening test (OECD422) in Wistar Rats with [REDACTED] [REDACTED] conducted by [REDACTED]. The test substance a hardener for coatings.

The study has been performed with the dose levels of 0, 75, 250, or 750 mg/kg bw/day via gavage with 11 male and 11 female rats per dose group.

The following findings were seen:

One female at 750 mg/kg bw/day died towards the end of the gestation period. It showed hunched posture and ruffled fur starting 14 days prior to the spontaneous death, accompanied by weakened condition and visible body weight loss. Severe ulcerations of the forestomach were observed at histopathological examination.

An increase in incidence and severity of ulceration/erosion of the glandular and forestomach, squamous hyperplasia and/or inflammatory cell infiltration in the submucosa of the stomach was observed in animals at 250 and 750 mg/kg bw/day. The lesions were considered to represent a localized stomach reaction to a repeatedly gavaged irritant test material.

No compound-related effects were observed at 75 mg/kg bw/day.



Company Sanitized

Sanitized Copy

United States Environmental Protection Agency – East

January 3, 2013

Page 2

[REDACTED] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted.

Sincerely,

Enclosures

9510160 VME, 1/3/13