# H.R. 2567, THE ANTIFREEZE BITTERING ACT OF 2005

## HEARING

BEFORE THE

## SUBCOMMITTEE ON ENVIRONMENT AND HAZARDOUS MATERIALS

OF THE

## COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

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## H.R. 2567, THE ANTIFREEZE BITTERING ACT OF 2005

## **TUESDAY, MAY 23, 2006**

## HOUSE OF REPRESENTATIVES, COMMITTEE ON ENERGY AND COMMERCE, SUBCOMMITTEE ON ENVIRONMENT AND HAZARDOUS MATERIALS, *Washington, DC.*

The subcommittee met, pursuant to notice, at 1:30 p.m., in Room 2322 of the Rayburn House Office Building, Hon. Paul Gillmor (chairman) presiding.

Members present: Representatives Wilson, Bass, Sullivan, Barton (ex officio), Solis, Stupak, Capps, Doyle, Schakowsky, Inslee, Baldwin, and Gillmor.

Staff present: David McCarthy, Chief Counsel for Energy and Environment; Tom Hassenboehler, Counsel; Jerry Couri, Policy Coordinator; Billy Harvard, Legislative Clerk; Dick Frandsen, Minority Senior Counsel; Lorie Schmidt, Minority Counsel; and Alec Gerlach, Minority Research Assistant.

MR. GILLMOR. The committee will come to order and before the Chair recognizes himself, I ask unanimous consent that all Members have five legislative days to submit opening statements for the record, and hearing no objection, that is so ordered.

The Chair recognizes himself for the purpose of delivering an opening statement. Normally, the hearings we have in this committee deal with issues that directly effect human health and the environment. Today's subject matter is geared more toward the questions involved in safeguarding animal health and the environment, and whether it is appropriate for the Federal government to create a national standard to help ease the impacts to interstate commerce by doing so.

News reports of pets being poisoned by drinking antifreeze have horrified many people and according to the Agency for Toxic Substances and Disease Registry, one of the main constituents of antifreeze, ethylene glycol, can significantly damage the kidneys, heart, and nervous system of humans, potentially resulting in fatalities, if not immediately treated. Concerns that pets or small children could be at such a risk to accidentally drinking spilled antifreeze have spurred three States into enacting legislation that requires a bittering agent be added to antifreeze to discourage both human and pet ingestion. In fact, 10 more States are considering requiring bittering agents. The nexus between interstate distribution of antifreeze products and multiple differing antifreeze recipe requirements in each State gives rise to the question of whether Congress should act. The bill that our subcommittee will consider today requires engine coolant, or antifreeze, that contains more than 10 percent ethylene glycol to include a bittering agent known as denatonium benzoate at a minimum, at a level that would make the coolant or antifreeze unpalatable to pets or small children.

In addition, and of interest to our subcommittee, the bill provides environmental liability protection for anyone who was not directly responsible for producing the bittering agent and was not grossly negligent concerning any environmental damage that may have been caused by its release. Some people argue that it is unfair to hold them liable for complying to law by adding a bittering agent that they did not make. And while I am inclined to be sympathetic to the antifreeze makers in this case, I also note that there is nothing in the bill that would deflect any liability for the other constituents of antifreeze that may be released into the environment and may of themselves cause contamination.

So I look forward to hearing the testimony from our witnesses today, and I want to thank them for their time and effort in being with us.

[The prepared statement of Hon. Paul Gillmor follows:]

# PREPARED STATEMENT OF THE HON. PAUL GILLMOR, CHAIRMAN, SUBCOMMITTEE ON ENVIRONMENT AND HAZARDOUS MATERIALS

The Subcommittee will come to order. Before the Chair recognizes himself, the Chair would like to ask Unanimous Consent that all members have 5 legislative days to submit opening statements for the record. Hearing no objection, it is so ordered.

In addition, the Chair would like to remind members that under the Standard Practices of the Committee, opening statements for the Chairman and Ranking Member will be five (5) minutes each and other members of the committee who is seated and recognized will be given three (3) minutes. Any member you wishes to waive their right to delivering an opening statement will be granted another three (3) minutes during their allotted time to ask questions.

The Chair now recognizes himself for 5 minutes for the purposes of delivering an opening statement.

Normally, the hearings we have in this committee deal with issues that directly affect human health and the environment, today's subject matter is geared more towards the questions involved in safeguarding animal health and the environment and whether it is appropriate for the Federal government to create a national standard to help ease the impacts to interstate commerce by doing so.

News reports of pets being poisoned by drinking antifreeze have horrified many people. According to the Agency for Toxic Substances and Disease Registry (ATSDR), one of the main constituents of antifreeze, ethylene glycol, can significantly damage the kidneys, heart and, nervous systems of humans; potentially resulting, if not immediately treated, in fatalities.

Concern that either pets or small children could be at such a risk to accidentally drinking spilled antifreeze has spurred three states into enacting legislation requiring that a bittering agent be added to antifreeze to discourage any human or pet ingestion. In fact, 10 states are considering requiring bittering agents in the antifreeze marketed and sold in their states. The nexus between interstate distribution of antifreeze products and multiple, differing antifreeze recipe requirements in each state begs the questions of whether Congress should act.

The bill that our committee will consider today requires engine coolant or antifreeze that contains more than 10 percent ethylene glycol, to include a bittering agent -- known as denatonium benzoate, at a minimum at a level that would make the coolant or antifreeze unpalatable to pets or small children. This requirement is closest to New Mexico's state law, but is similar to others.

In addition, and of most interest to our subcommittee, the bill provides environmental liability protection for anyone who was not directly responsible for producing the bittering agent. Some people argue that it is unfair to expose antifreeze makers to liability for complying.

Although I have not made up my mind fully about this bill, I am inclined to be sympathetic to the antifreeze makers in this case. I note that nothing in the bill would deflect any liability for other constituents of antifreeze that may be released into the environment and, of themselves, cause contamination. In addition, with the current liability scheme in most environmental laws, I would be surprised if an environmental regulatory or enforcement agent could not get a regulated release remediated and paid for with the full panoply of authorities now available to Federal and state officials. I am open, though, to being convinced otherwise.

I look forward to hearing the testimony from our witnesses today and thank them for their time and effort to be with us.

I now yield back the balance of my time and recognize the Gentlelady from California and the Ranking Member of the Subcommittee, Mrs. Solis. For 5 minutes for the purposes of delivering an opening statement.

MR. GILLMOR. And I yield back the balance of my time and I recognize the Ranking Member of the subcommittee, Mrs. Solis.

MS. SOLIS. The yanking member?

MR. GILLMOR. The yanking member.

MS. SOLIS. Thank you.

MR. GILLMOR. Not in California, right?

MS. SOLIS. No. Thank you, Mr. Chairman, and good afternoon to you all and thank you, Congressman Ackerman, for being here, as well. I would like to thank all the witnesses that are going to be joining us and providing testimony. But before I address the legislation, I would like to comment on a trend which concerns me regarding our subcommittee and our committee; specifically, legislation considered in this subcommittee over the last six months has consistently preempted the rights of our States, particularly when large corporate interests find more protective State laws inconvenient. The same legislation has often shielded actors from liabilities for environmental contamination, much of which risks public health and transfers the burden of cleanup onto our communities.

For example, on November 16, 2005, this subcommittee held a hearing on concentrated animal feeding operations and superfund laws.

Legislation addressing this issue exempts large corporations like Tyson Food from the superfund law. On March 2, 2006, the subcommittee held a hearing on H.R. 4591, legislation to implement the Stockholm Convention. Just last week the legislation included State preemption passed this subcommittee on a party line vote. And today we are discussing H.R. 2567, the Antifreeze Bittering Act of 2005 which both preempts State law and provides liability shield to manufacturers of antifreeze, such as Honeywell, from public health and environmental damages.

I have been a staunch supporter of strong laws to protect our health and the wellbeing of our public and animals, and I regularly support efforts to achieve goals such as promoting animal welfare and believe the intent behind the bill is good; that is why I find the legislative text even more troublesome and I am concerned that the solution provided in the legislation does not appropriately or adequately address the problem. First, I question the ability of DB, that is the denatonium benzoate, to protect animals. While I understand the California Integrated Waste Management Board concluded that dogs have exhibited some symptoms indicating a dislike for DB upon its ingestion, the Animal Poison Control Center has reached other conclusions.

Back on March 30 of 2004, the Animal Poison Control Center concluded that, and I quote, "We are not aware of any well-controlled, published scientific research demonstrating that dogs can be consistently protected from poisoning through the addition of taste adversive agents such as DB." The Animal Poison Control Center went on to express concern that pet owners will have a false sense of security if products containing taste adversive substances were marketed as being safer. I share their concern. The Consumer Product Safety Commission also questions the effectiveness of the bittering agent and wrote that there is no evidence that DB or any other possible adversive agent is actually effective at limiting the ingestion of consumer products.

I believe we need to study the effectiveness of DB, the bittering agent which is mandated by the bill. As the Consumer Product Safety Commission wrote, "The use of adversives should not be considered for regulation until the effectiveness of these substances are actually limiting ingestion is demonstrated." Second, and I am concerned by conflicting reports about the impact that this will also have on our environment. While the California Integrated Waste Management Board has stated that DB readily degrades, several other studies indicate that it is not biodegradable. The Environmental Defense includes DB on its list of suspected neuro-toxicants and the Congressional Research Service concluded that data on toxicity and exposure are too sparse to provide sound, scientific basis for assessing the environmental risk of DB. Finally, the EPA included in its written testimony that it has not conducted a full risk assessment nor is there an available extensive database of toxicity or environmental information on this product. Yet, even without this information, the bill includes a liability shield to protect the manufacturers of antifreeze from cleanup costs, leaving again our communities to hold the cost or the bag. Ultimately, I refuse to believe that the only viable solution to the problem is one that preempts our States, broadly undermines our environmental and public health protections, establishes a false sense of security for pet owners, and transfers a burden of possible cleanup onto our communities and water providers. It is only prudent to have a thorough understanding of the effectiveness of the product we will be mandating before requiring its inclusion.

I encourage my colleagues to look for solutions beyond the legislation and I am willing to work with you on that. I would also request unanimous consent to submit for the record a letter by Governor Bill Richardson of New Mexico wherein on May 22<sup>nd</sup> he states his opposition to this bill. I yield back the balance of my time.

[The prepared statement of Hon. Hilda Solis follows:]

### PREPARED STATEMENT OF THE HON. HILDA L. SOLIS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Good afternoon.

I would like to thank our witnesses for joining us today and recognize our colleague, the Honorable Gary Ackerman, who will be joining us.

Before I address this legislation, I would like to comment on a trend which concerns me.

Specifically, legislation considered in this Subcommittee over the last six months has consistently preempted the rights of our states, particularly when large corporate interests find more protective State laws inconvenient.

The same legislation has often shielded actors from liability for environmental contamination, much of which risks public health and transfers the burden of cleanup onto our communities.

For example, on November 16, 2005, this Subcommittee held a hearing on concentrated animal feeding operations and Superfund laws.

The legislation addressing this issue exempts large corporations like Tysons Food from the Superfund law.

On March 2, 2006, this Subcommittee held a hearing on H.R. 4591, legislation to implement the Stockholm Convention.

Just last week this legislation – including state preemption – passed this Subcommittee on a party line vote.

And today, we discussing H.R. 2567, the Antifreeze Bittering Act of 2005, which <u>both</u> preempts states laws AND provides a liability shield to manufacturers of antifreeze – such as Honeywell – from public health and environmental damages.

I have long been a staunch supporter of strong laws to protect the health and wellbeing of people and animals.

I regularly support efforts to achieve goals such as promoting animal welfare and believe the intent behind this bill is good.

That is why I find the legislative text even more troublesome.

I am concerned that the solution provided in this legislation does not appropriately or adequately address the problem.

First, I question the ability of denatonium benzoate [DB] to protect animals.

While I understand the California Integrate Waste Management Board concluded that dogs have exhibited some symptoms indicating dislike of DB upon its ingestion, the Animal Poison Control Center has reached other conclusions.

On March 30, 2004, the Animal Poison Control Center concluded that "we are not aware of any well-controlled published scientific research demonstrating that dogs can be consistently protected from poisoning through the addition of taste aversive agents including DB."

The Animal Poison Control Center went on to express concern that "pet owners will have a false sense of security if products containing taste aversive substances were marketed as 'safer'."

I share their concern.

The Consumer Product Safety Commission also questions the effectiveness of this bittering agent and wrote that "there is no evidence that denatonium benzoate or any other possible aversive agent is actually effective at limiting ingestions of consumer products."

I believe we need a study the effectiveness of denatonium benzoate, the bittering agent which is mandated by this bill.

As the Consumer Product Safety Commission wrote "the use of aversives should not be considered for regulation until the effectiveness of these substances to limit ingestion is demonstrated."

Second, I am concerned by conflicting reports about the impact of DB on the environment.

While the California Integrate Waste Management Board has stated that DB readily degrades, several other studies indicate that it does not biodegrade like ethylene glycol.

Environmental Defense includes DB on its list of suspected neurotoxicants and the Congressional Research Service concluded that data on toxicity and exposure are too sparse to provide a sound scientific basis for assessing the environment risk of DB.

Finally, the EPA included in its written testimony that it has "not conducted a full risk assessment, nor is there available an extensive database of toxicity or environmental fate information on DB."

Yet, even without this information, H.R. 2567 includes a liability shield to protect the manufacturers of antifreeze from cleanup costs – leaving our communities holding the bag.

Ultimately, I refuse to believe that the only viable solution to this problem is one that preempts our states, broadly undermines our environmental and public health protections, establishes a false sense of security for pet owners, and transfers burden of possible cleanup to our communities and water providers.

It is only prudent to have a thorough understanding of the effectiveness of the product we would be mandating before requiring its inclusion broadly.

I encourage my colleagues to look for solutions beyond this legislation and am willing to work with them to achieve that.

Thank you again for being here.

I yield back the balance of my time.

MR. GILLMOR. Is there objection to including the letter from Governor Richardson? The gentlelady from New Mexico.

MRS. WILSON. Mr. Chairman, reserving the right to object, I would also like to include the Governor's letter of April 17<sup>th</sup> supporting this bill in the record.

MR. GILLMOR. Did he support it before or after he opposed it?

MRS. WILSON. I think he opposed it after he supported it.

MR. GILLMOR. Oh.

MRS. WILSON. With the consent of the gentlewoman from California, why don't we just put both letters into the record and let the public decide what the Governor of New Mexico supports?

MS. SOLIS. That would be fine.

MR. GILLMOR. Without objection, hearing none, both letters from the Governor from New Mexico will be included in the record.

[The information follows:]



## State of New Mexico Office of the Governor

April 17, 2006

Honorable Joe Barton Chairman, Energy and Commerce Committee U.S. House of Representatives Washington, D.C. 20515

#### VIA FAX: 202-225-1919

Dear Mr. Chairman:

**Bill Richardson** 

After the death of Scooby, a dog who had survived a gunshot wound only to be deliberately poisoned by antifreeze, the citizens of New Mexico galvanized around a state bill to help prevent any more such tragedies. They had reason to worry: On a national basis, not only do thousands of animals a year die after ingesting antifreeze, but well over 1,000 children, and many more adults, are also poisoned by the sweet but highly toxic substance. New Mexico is not immune from this problem. In a one-year period here, there were 73 cases of human antifreeze poisonings, with two deaths.

Our Department of Health concluded that adding a bittering agent in antifreeze to make it unpalatable should significantly reduce animal exposures and unintentional human exposures. Based on the experiences of Oregon and California and on the scientific evidence of its appropriateness for the purpose, as well as its long history of use, the New Mexico law requires the inclusion of denatonium benzoate as a bitterant in ethylene glycol antifreeze.

The New Mexico law is virtually identical to the bill before your committee, H.R. 2567 the Antifreeze Bittering Act. We also adopted the policy of "assigned liability." to ensure that the antifreeze manufacturers and the denatonium benzoate manufacturers would be held legally responsible for any problems arising out of the use of their respective products.

We're very proud of having taken this common-sense approach to addressing a situation that results in unnecessary medical emergencies, suffering, and sometimes death for humans and animals alike. But we can also see the need for a uniform, national standard. As it happens, several of our own localities passed their own ordinances while waiting for the state legislature to act. A patchwork of laws across the country will serve neither the public nor the free flow of commerce. I therefore respectfully urge Congress to pass H.R. 2567/S. 1110. Doing so will ensure that all citizens and their belowd pets including all of us in New Mexico will be protected through a uniform national law.

Sincerely, buy ful Bill Richardson Governor

State Capitol · Room 400 · Santa Fe New Mexico 87601 · 605-476-2200 · WHIMI CONSTRUCTOR CARE TO VIO



## State of New Mexico Office of the Governor

Bill Richardson Governor

May 22, 2006

The Honorable John Dingell Ranking Member House Energy & Commerce Committee 2328 Rayburn House Building Washington, D.C. 20515

Re: HR 2567

Dear Ranking Member Dingell:

I am a strong supporter of legislation that will protect animals from dangerous contact with antifreeze by the addition of a bittering agent. As I mentioned in my April 17 correspondence to you, New Mexico enacted sensible legislation on this issue and I believe the Congress should also act.

However, I am informed that my general support for congressional action on this issue has been interpreted as support for exemption from the federal superfund law and preemption of state action. I do not support exemptions from the superfund law, and I do not support congressional pre-emption of state action on these controls. While a federal law is necessary, it should be a floor for action by the states and should not undermine existing federal law regarding management of toxic materials.

I appreciate your hard work on this issue and will continue to work with you to achieve a good result for the Nation.

Sincerely. i Richarton

Bill Richardson Governor

cc: Chairman Joe Barton Representative Hilda Solis

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MR. GILLMOR. Are there further opening statements? The gentlelady, Mrs. Wilson. Well, let me first go to--I didn't notice that our Chairman of the full committee had come in. We will go to Mr. Barton first.

CHAIRMAN BARTON. I am happy to defer to the sponsor of the bill, I think. Well, thank you, Mr. Chairman, for holding this hearing. Thank you, Mr. Ackerman, for being here. I am interested to see what you are

going to do with the props in front of you; which of those you are going to drink and which you are not going to drink.

We are here to discuss H.R. 2567, the Antifreeze Bittering Act of 2005. This bill would amend the Federal Hazardous Substance Control Act to require engine coolant and antifreeze to contain a bittering agent to protect from the accidental poisoning of children and animals. I understand that the Consumer Product Safety Commission believes that adversive agents can help prevent accidental poisoning in the home. I am also told that denatonium benzoate, or DB, the agent that is the subject of this legislation, has been present in many household products for years. Several States, including New Mexico, California, and Oregon require it or something like it to be in antifreeze and engine coolants.

As we think about whether the Federal government should create a national standard to ease the impact on interstate commerce and to mirror the success that States have had in preventing poisoning, I am interested in learning more about how these State programs really work to protect children and animals. I hope our witnesses today can also shed some light on the concerns of the others over the inclusion of limited liability protection for the manufacturers and distributors of engine coolant and antifreeze, who would be subject to this mandate. I want to thank the subcommittee Chairman for holding this hearing and look forward to it. Hopefully, we can get a consensus that would enable us to have a markup and move the bill.

### [The prepared statement of Hon. Joe Barton follows:]

# PREPARED STATEMENT OF THE HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Thank you Mr. Chairman for holding this hearing on HR 2567, the Antifreeze Bittering Act of 2005, a bill that amends the Federal Hazardous Substances Control Act to require engine coolant and antifreeze to contain a bittering agent to protect from the accidental poisoning of children and animals.

I understand that the Consumer Product Safety Commission believes that "aversive" agents can help prevent accidental poisoning in the home. I am also told that denatonium benzoate, or DB, the agent that is the subject of this legislation, has been present in many household products for years. Several states, including New Mexico, California, and Oregon, require it, or something like it, to be in antifreeze and engine coolants.

However, as we think about whether the Federal government should create a national standard to ease the impact on interstate commerce and to mirror the success states have had in preventing poisoning, I am interested in learning more about how these state programs really work to protect children and animals. I hope the witnesses today can also shed some light on the concerns of others over the inclusion of limited liability protection for the manufacturers and distributors of engine coolant and antifreeze who would be subject to this mandate. I thank all the witnesses before the Subcommittee today and return the balance of my time.

MR. GILLMOR. The gentleman from Michigan, Mr. Stupak; he is not here. The gentlelady from California, Mrs. Capps.

MS. CAPPS. Thank you, Mr. Chairman. I appreciate this subcommittee's effort to protect children and animals from the dangers of ingesting antifreeze, a goal, I believe, we all support wholeheartedly and I appreciate the honorable colleague of ours, Gary Ackerman, for being here as our first panelist. I commend him and the bill supporters for trying to find a solution to a tragic problem.

I now have three principal concerns with H.R. 2567 as it is currently written. These have been stated in part already, so I will be brief, but I believe first we need to learn more about the possible impact of denatonium benzoate or DB on human health and the environment before its widespread use is mandated. The scientific evidence on the effects of DB is limited and what is known suggests that more study is warranted. For example, some studies have shown DB persists in the environment and can spread throughout the water and the Congressional Research Service has reported, and I quote, "Few studies have been conducted to assess the effectiveness of denatonium benzoate in discouraging tasting, swallowing or otherwise repelling wildlife, pets or children." And the Consumer Product Safety Commission has concluded, and I quote, "There is no evidence that DB or any other possible adversive agent is actually effective at limiting ingestion of consumer products."

Second, the bill provides, and this is the difficult one for my State, which has its own provisions, this bill provides a provision that preempts States from regulating antifreeze bitterants unless they are identical to H.R. 2657. I don't think we should make it harder for States to protect the health and safety of their residents. And finally, the bill waives all forms of liability for companies making or handling DB, even if the use of this chemical causes environmental damage, personal injury or even death. This waiver would apply even if children or animals are injured or killed by DB, jeopardizing the very people or pets the bill purports to protect.

We shouldn't limit liability for any product that could cause health or environmental harm, eliminate manufacturers' incentives to create safer products, or shift cleanup costs away from responsible parties. Mr. Chairman, the implications of the use of DB and the future effects of a liability waiver must be the subject of many more hearings, in my opinion, before this bill moves further. That doesn't mean it is not a worthwhile goal, and I do look forward to working with you, to working with Gary Ackerman, to working with the sponsors of the bill to make, as well as the many supporters, to pass as strong a bill as we can that makes antifreeze a safer product. I yield back.

MR. GILLMOR. The gentlelady from New Mexico.

MRS. WILSON. Thank you, Mr. Chairman, and thank you for holding this hearing. I particularly wanted to thank Gary Ackerman from New York for your leadership on this issue, along with Mr. Rohrabacher from California. You have been real supporters and advocates for changing some of the rules to take what is a very hazardous substance and make it less attractive to both children and to animals. I also wanted to thank and to introduce Dr. Melinda Eyrich, who is here from Albuquerque. She is a veterinarian and has been a veterinarian for 15 years in practice in New Mexico and 7 years as an emergency veterinarian and we thank you for being here, Dr. Eyrich.

This is a bipartisan bill and over the last 2 Congresses, 19 Democrats have, at one time or another, sponsored this piece of legislation for a very good reason. In the last year alone, 74 poisonings have happened in the State of New Mexico of children from drinking antifreeze and thousands of animals have been injured or killed from drinking antifreeze. The State of New Mexico passed a law in March of 2005; it was enacted in July of 2005 and this legislation is identical to the law that was passed in New Mexico. So what is this bitterest substance known to man that this legislation will require be put into antifreeze? It is a substance called DB. I am not even going to try to correctly pronounce its chemical name.

But it was approved by the FDA in 1963. We have 40 years of experience with this particular compound being added to consumer products to make them bitter, mostly so that children won't eat them; nail polish, hair spray, crayons, bubble bath, shampoo, eye shadow, ink, hand sanitizer, windshield wash, laundry detergent, fabric softener, perfume all have DB in it so that children won't eat it because it is too bitter. That is what we are asking this legislation to add to antifreeze.

The United Kingdom, Japan, Australia, and France all have similar laws and it would cost three cents on the gallon. There is an unusually broad group of supporters of this legislation; the Humane Society, the antifreeze manufacturers, the American Academy of Pediatrics, the American Veterinary Medical Association, and others, and for very good reason. This is a product that is very attractive to children and to animals and we need to require that enhanced safety be put in place.

I would all also note, with respect to safety, it took 17 years to be able to scientifically prove that putting safety caps on medicines and household chemicals helped keep children safe. We don't need to wait 17 years to see if this will work for antifreeze. We need to take safety precautions so that children are less likely to drink antifreeze and animals aren't, either. Thank you, Mr. Chairman.

[The prepared statement of Hon. Heather Wilson follows:]

# PREPARED STATEMENT OF THE HON. HEATHER WILSON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW MEXICO

Mr. Chairman, I would like to thank you for holding this hearing today on the Antifreeze Bitterant Act, H.R. 2567. I would also like to introduce one of the witnesses today on the third panel, Dr. Melinda Eyrich. Dr. Eyrich is from Albuquerque, New Mexico, and has been a veterinarian for 15 years. I would like to welcome Dr. Eyrich and I look forward to her testimony and the testimony of all the witnesses.

Antifreeze poisoning is a real danger. Because antifreeze tastes and smells sweet, it is ingested by children and pets. Last year 74 people in New Mexico were poisoned by antifreeze, and many more animals were poisoned, with several animal deaths. Losing a pet is not an easy thing. Just ask anyone who has lost their pet. Lisa Hecker of New Mexico lost her dog when someone put dog food swimming in antifreeze out in the arroyo next to the road where they live in September 2004. Nine dogs and 2 cats were killed by antifreeze poisoning in her neighborhood within a two week period. But we can do something to stop these poisonings, whether they are intentional or accidental.

The City of Albuquerque passed a law in 2004 to include the bittering agent denatonium benzoate in antifreeze, and the State of New Mexico followed suit in 2005. Denatonium benzoate is also a required additive to make antifreeze bitter in the UK, Japan, Australia, and France. The United States should follow suit.

Making antifreeze bitter only costs about 3 cents per gallon. This seems like a small price to pay to keep our children and our pets safe. Frankly, I don't see how anyone could oppose this legislation.

MR. GILLMOR. The gentleman from Michigan.

MR. STUPAK. Thank you, Mr. Chairman. I will be in and out of this hearing, so I am going to pass on my opening statement.

MR. GILLMOR. Mr. Doyle.

MR. DOYLE. Thank you, Mr. Chairman. I want to thank you for holding this hearing so that this committee can fully investigate the effect that H.R. 2567 will have on our families, our environment and the antifreeze industry itself. At a time when far too many bills skip all or part of this committee's legislative process, Mr. Chairman, I want to applaud you for allowing us to fully vet this bill through normal order. I am a cosponsor of this bill, and I am a long-time supporter of efforts to protect our pets from harm, be it from physical abuse or accidental means, such as which result from their consumption of antifreeze. Consequently, I fully support adding a bittering agent to antifreeze and think it is long overdue. However, I have some concerns with the mandate that one specific bittering agent must be used in order to make antifreeze less appealing to our pets and small children.

I believe we can achieve our goal of making antifreeze distasteful to our pets without potentially creating a new threat to the environment. As many of our witnesses will testify today, we simply do not know what effects Bitrex may have if released into our environment through a spill. Since its been described as the most bitter substance we could possibly add to antifreeze, the danger of a spill and a contamination of any local drinking water is a real concern and something that needs further examination. Because we don't know what dangers this bittering agent may or may not pose to our environment and our health, I support the liability protection waivers of this legislation because I find it a bit irresponsible that this committee and this Congress would mandate that a company must include it in their product without giving that company some protections against being sued if the bittering agent does, in fact, end up causing widespread damage.

Don't get me wrong. I generally do not support blanket liability waivers for any industry and believe strongly that if you are the one who pollutes, you are the one who should pay for the cleanup. However, in this particular circumstance, industry is being ordered to include a specific substance in their product when neither I nor you nor any of the experts in this room can tell for certain that the substance is safe. That would sort of be like ordering a shower maker to add an electrical unit to its product in the name of making it more energy efficient without any testing whether the electrical unit posed any risk of electrocution.

Simply put, Mr. Chairman, until we know for certain what risk Bitrex poses, I must support the waiver of liability provisions contained in this legislation. In conclusion, I fully support the intention of this legislation. I hope that we can work together to answer the questions that Bitrex poses. I know that we can find a way to make antifreeze less appealing to children and pets while simultaneously protecting our environment and I look forward to working with you to achieve this goal. Mr. Chairman, I yield back the balance of my time.

MR. GILLMOR. The gentleman yields back. The gentlelady from Illinois.

MS. SCHAKOWSKY. Thank you, Chairman Gillmor and Ranking Member Solis, for holding today's hearing on antifreeze products. I am concerned that what was a bill that would protect both children and pets from consuming deadly antifreeze is now a bill that will shield the chemical industry from willful misconduct and preempt strong State laws. I want to say from the outset that I have been a strong supporter of this legislation. I was a cosponsor in the last Congress of the Antifreeze Bittering Act along with 132 others. I wouldn't cede ground to anyone in my support for animals and the Humane Society and the Doris Day Animal League and the veterinarian that we will hear from. I am sure I am going to agree with you on everything, but we need to, in my view, collect more evidence to analyze the environmental impact and adverse effects of DB before legislating on this issue.

The problem before the subcommittee is clear. Ethylene glycol, in which the antifreeze most commonly used in the United States, is registered by the EPA as a toxic substance and is ingested by thousands of children and pets each year. That is indisputable. The solution, however, is somewhat less clear. Ethylene glycol isn't the only type of antifreeze on the market in the United States. We should consider whether promoting a safer version of antifreeze based on propylene glycol is a viable option. And while a number of studies indicate that DB has a bittering effect that deters both pets and humans from consuming it, its environmental impact remains unclear. We may discover alternative bittering agents that would both have a taste adversive effect and have no demonstrable impact on the environment.

The problem with this bill, first it expands the liability waiver to include environmental damage, even though some research suggests that DB is not biodegradable and could contaminate drinking water, eliminates the willful misconduct exception that was included in the previous versions of the legislation, mandates the use of DB as the bittering agent. It preempts stronger State laws like those in California and Oregon, which would allow the use of adversive agents other than DB, allowing science not speculation to dictate the best option.

I know that the chemical industry has reversed its position on this issue since it was considered in 2004. At that time, the Consumer Specialty Products Association argued "There is no credible scientific evidence showing that the inclusion of bitterants in antifreeze has resulted in a reduction in incidents of accidental poison." The CPSA submitted a number of studies to the Library of Congress to document the inconclusiveness of that science. But now that the liability waiver has been broadened to include environmental damage and eliminated the exception for willful misconduct, the industry is here today testifying in support of the legislation.

My view is that before passing a bill that wipes out some consumer and environmental protections and preempts State laws, that we have to ensure that we are acting based on conclusive science in support of a solution that will protect our children, our pets, and the environment. Thank you, Mr. Chairman.

MR. GILLMOR. The gentlelady from Wisconsin.

MS. BALDWIN. Thank you, Mr. Chairman. Today's hearing is an important one. I share the concerns raised by my colleagues about the dangers of ingesting engine coolant and antifreeze products. Last Congress I was pleased to cosponsor the antifreeze bittering legislation. Last session's bill provided a balanced approach to protect our children, animals, and our environment. It would have held liable those parties responsible for environmental damage or those liable for willful misconduct. And it would also have allowed States to protect the safety of their citizens by establishing their own standards for the use of antifreeze. But this Congress, the bill is different.

Mr. Chairman, I thought long and hard about this measure and my co-sponsorship of it and despite supporting last session's bill and certainly the intent behind the bill before us this session, I concluded that the language in this version would simply cause more harm than good. Specifically, I am concerned about the strict requirement that denatonium benzoate be used as the bittering agent, despite the lack of sufficient evidence providing that DB is safe for the environment. In studies sponsored by antifreeze manufacturers, evidence shows that DB does not biodegrade, resulting in its being passed through to our water treatment plants. Further, studies show that DB can accumulate in the groundwater resulting in the contamination of area wells.

In all, the science is just not behind DB, at least it is not behind DB to the extent that we should mandate its use, exempt manufacturers from liability, and cross our fingers and hope that our environment will not suffer. Valid concerns about the State preemption provision were also brought to my attention. States should have the ability to determine the appropriate means for protecting their citizens, just as our longstanding environmental laws explicitly allow them to do.

Finally, I am troubled that antifreeze manufacturers get a free pass from any damages their products cause to the environment. It seems like just yesterday when we refused to exempt MTBE manufacturers from liability during the Energy Policy Act debate, that we should apply the same logic here today. Antifreeze manufacturers, producers and distributors should be held liable for spills or other damages caused by their ordinary use, negligence or willful misconduct. Broad legal immunity fails to protect our citizens and our environment.

Mr. Chairman, in all there are better ways for us to make antifreeze into a safer product for children and animals. No one wants to see them harmed from ingested antifreeze. But we are setting a bad precedent by closing the courthouse doors, preventing States from taking action, and mandating the use of the product when we are not quite sure about all the risks. I look forward to hearing about how we can find a more balanced approach to protecting the safety of our children and animals while also protecting our environment and the rights of the citizens and our States. Thank you, Mr. Chairman.

MR. GILLMOR. Are there further opening statements? If not, we will turn the chair to Mr. Ackerman.

[Additional statements submitted for the record follows:]

# $\label{eq:prepared Statement of the Hon. Charles F. Bass, a Representative in Congress from the State of Michigan$

Thank you Chairman Gillmor for holding this hearing today about the proposed legislation to federally mandate the addition of an aversive agent in antifreeze. Sadly,

every year children and animals become ill from the unintentional -and sometimes intentional poisoning - from drinking this commonly available toxic substance. Especially coming from the Northeast, it is not uncommon for households to have a gallon of antifreeze stored in their garage. Over the years, the industry has taken significant steps in preventing unintentional poisoning by including foil seals and safety caps on their products to prevent children and animals from getting a hold of this highly toxic product. Unfortunately, human error and just the simple nature of the substance being in the environment, there are still a significant number of cases of children and animals becoming extremely ill and in some extreme circumstances dying from kidney failure each year.

Several states have passed legislation to require the inclusion of bittering agents to antifreeze. Bittering agents has been found to be successful in preventing the consumption of toxic but sweet tasting chemicals. Currently, there are several additional states considering implementing similar legislation. However, due to our increasing mobile society which carries this substance daily across state lines and that the distribution of antifreeze is an interstate commerce issue, it is clear that Congress needs to consider federal regulations on the inclusion of bittering agent -denatonium benzoate (DP) - in antifreeze. It is impractical to have a patchwork of 50 different regulations on antifreeze. Additionally, it is important to note that DP has been used for years in other products as a bittering agent. The U.S. Bureau of Alcohol, Tobacco, and Firearms requires that industrial alcohol products contain a bittering agent and is specifically used in deodorants, shampoos, soaps, room deodorizers, and disinfectants.

In testimony submitted by Mr. Tom Bonazquisti, the Director of Water Quality and Production, the water treatment industry expresses concerns over the use of DB in antifreeze and its possible environmental and health impact it would have if the substance escapes into the environment and possibly into our water systems. However, I hope Mr. Bonzaquisti will take a moment to comment on what type of impact DB has had since it is found in many common household products since 1963 and is regularly released into our water sewer systems. If DB does cause a potential environmental hazard, I think then the issue should be addressed by this Committee is whether we continual use bittering agent in household products.

Currently, H.R. 2567, the Antifreeze Bittering Act is pending before this Committee. This legislation is a bipartisan effort that has been part of ongoing discussions between chemical industry and environmental groups. The Senate has recently marked up the companion bill and added language regarding a study to ensure that DB or alternative bittering agents have no adverse affect on the environment. Due to its long use in common household products and its use in three states, there should be significant amount of data that can be looked at to make a determination. I hope that the witnesses will discuss their take of the changes made in the Senate.

The addition of a bittering agent to antifreeze will assist in preventing the unnecessary death of wildlife and family pets. This legislation appears to be a commonsense strategy toward this goal and has developed out of discussions between the various stakeholders. I look forward to the testimony from our witnesses and thank them for coming before the Subcommittee.

# PREPARED STATEMENT OF THE HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. Chairman, today the Subcommittee is holding a hearing on H.R. 2567, the Antifreeze Bittering Act of 2005, a bill that amends the Federal Hazardous Substances Act to require that a bittering agent, denatonium benzoate, be added to antifreeze sold commercially. The hearing today provides the opportunity to begin the process of

answering some very necessary questions about this legislation. Let me highlight a few of them:

- Why have the manufacturers of denatonium benzoate declined to provide scientific data on the environmental fate and environmental toxicology of denatonium benzoate?
- Do we have full toxicological, exposure, and risk evaluations on the bitterant denatonium benzoate or other bittering agents before us and available for Congress and the public to review?
- Should the Congress be mandating a market for a product, denatonium benzoate, that is manufactured almost exclusively in other countries?
- What scientific evidence shows that the inclusion of bitterants in automotive products has resulted in a reduction in incidents of accidental poisoning?
- Has the Environmental Protection Agency (EPA) reviewed the numerous scientific studies about denatonium benzoate? Has the EPA rendered a conclusion as to whether it is safe if released in the environment?
- Should Congress provide broad legal immunity for the use of denatonium benzoate, including a liability exemption from the Superfund statute?
- Should we consider other options, such as the use of propylene glycol, as an alternative to ethylene glycol?
- Should we reverse 30 years of precedent in our pollution statutes by preempting State laws that may adopt more effective aversive agents or allow the use of aversive agents that are less harmful to the environment, or by preempting laws that maintain liability for environmentally harmful releases?

Mr. Chairman, while the goal of this legislation is worthy, we need answers to these questions before we proceed, and I look forward to the testimony of our witnesses.

# PREPARED STATEMENT OF THE HON. FRANK PALLONE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. Chairman, thank you for holding this hearing.

As a strong supporter of animal rights, I recognize the need to protect our children, pets, and wild animals from the accidental ingestion of ethylene glycol, the main ingredient in automobile antifreeze.

Still, I have serious concerns about whether H.R. 2567 as written will actually prevent unnecessary ingestion. I also have concerns about changes in this bill from its original form in the 108th Congress, when it was introduced as H.R. 1563 and had widespread support from members including myself.

First is the requirement in the new bill to mandate the use of denatonium benzoate, or DB, as the bittering agent -- and not allow the use of other agents. Scientific evidence at this point is inconclusive as to whether DB will prevent or inhibit ingestion and on whether the widespread use of DB is environmentally safe.

Furthermore, mandating the specific levels of DB to be used appears to me to be micromanagement of the worse kind. The result would likely be that we effectively prevent the development and use of other, possibly safer, antifreeze solutions or bittering agents.

I am also concerned that the bill selects a bittering agent made by only four manufacturers, none of which are in the United States.

These manufacturers have not released full data on the composition of their DB products despite being requested to do so. While this may be their right, our obligation as policymakers is to ensure that DB is safe and effective before mandating its use in the United States.

EPA will testify today that there is just not enough information to make a decision on the safety of releasing DB into the environment. We need additional time to gain the information necessary to understand what we are potentially going to release into our environment and could harm the same people and pets that we are seeking to protect.

I also cannot support legislation that would require the use of an agent of unknown composition and then release the companies who use it from any liability. Dating back to the debate over MTBE and other substances, there is a disturbing trend in Congress towards giving companies a free pass from pollution. Ultimately, the American people end up paying the bill when a liability waiver covers a chemical that turns out to have serious environmental impacts.

Finally, I am concerned about the state preemption language in this bill. I strongly support the ability of individual states to go beyond federal regulations. New Jersey frequently leads the nation in progressive environmental protections, and I cannot support any effort to infringe on their right to do so. The bill before us explicitly prohibits states from implementing more stringent protections or substituting safer and more effective bittering agents. I fail to see how such a restriction is a benefit to the people and pets we are seeking to protect.

I am interested in hearing from the witnesses on these matters, and I hope that we are able to fashion some sort of solution to all of the concerns surrounding this legislation.

Thank you, Mr. Chairman.

## STATEMENT OF HON. GARY L. ACKERMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

MR. ACKERMAN. Thank you very much, Chairman Gillmor and Ranking Member Solis. I listened to everybody's opening statement. Everybody is right. Welcome to the happy hour. Let me tell you a couple of things before we talk about accidental poisonings. Orlando, Florida; Lake Mary woman faces a charge of attempted murder after authorities accused her of giving her husband a glass of antifreeze. Marietta, Georgia; Lynn Turner convicted of poisoning her husband with antifreeze, sentenced to life in prison. She is also scheduled to go on trial for the antifreeze poisoning, subsequently, of her firefighter boyfriend. Cambridge, Massachusetts; Kevin Keown, a talk show host, arrested and accused of murdering his wife by spiking her Gatorade with antifreeze. Belton, Missouri; Michelle Hollis, arrested and charged with first degree murder, allegedly killing her husband by poisoning him with antifreeze. Albridge, New Jersey; Maryann Neabor, charged with killing her brother-in-law, spiking his fruit drink with antifreeze. Kansas City, Kansas; Ralph Trout and Donna Ozuna Trout charged with attempted murder for trying to kill the mayor and the mayor's family by sending them cupcakes and root beer laced with antifreeze. Omaha, Nebraska; Maureen Clamback sentenced to up to 26 years in prison for spiking a bottle of strawberry margarita mix with antifreeze, trying to kill her sister-in-law.

All this is what we have discovered during the past two years and I am sure there is a lot more that we will never know of. And why is this becoming the weapon of choice for murder? It is because it tastes so sweet. Children taste it, they want more; pets taste it, they lap it up. This is what the antifreeze looks like. It looks very much like all of these soft drinks and if you want, I will taste each and every one of them. They are soft drinks and they taste sweet. I am not going to taste this one.

This is that substance that we are all having such great difficulty pronouncing. This is DB and it is, we are told, the bitterest agent known on earth, worse than sucking a thousand lemons. And two drops of this, costing maybe two pennies for the cost plus the manufacture plus the mixing it in, two drops of this in the antifreeze per gallon, there you go, will now make the antifreeze bitter, very bitter. You may not think its bitter; I am not going to taste it. But if you would allow me to just move these things out of the way and do what some people would call New York's three card Monty thing, and ask you which one you would prefer to drink, I don't think anybody would play Russian Roulette with these stakes.

And although maybe one is a little darker than the other, I assure you, if we spilled them on your table or in your garage or in your driveway, they would all look exactly the same. With one exception; that if you tasted any one of them, nothing would happen to you. With one exception; if you tasted the one with DB, you would not taste anymore, not because of it being unhealthy, the unhealthy part is from this; but because of the bitter, extremely bitter taste that it has.

Now, the question is this dangerous? This can kill you. It has, and I am not even addressing the deliberate killings. We don't know what that amounts to and evidently, there is a spate of them now that people have discovered how to do it and how to slip your friend a mickey at a party and you know, whatever and them enjoying it. You put this in it, they can tell the difference. I am worried more about the 1,400 kids that have been poisoned last year. If we wait the 10 years that it takes for other things to be decided, that is 14,000 kids are going to be poisoned. Why? Because of inaction, because of uncertainty.

Well, you may ask and you have in the opening statements of some, how do we know about this stuff? How do we know about DB? And that concerns me, also. But if you do a little research and see what our society is doing right now, those of us who get our nails manicured; yes, I am one of them. We just got this down in CVS down the block, at CVS drugs, right off the shelf. So you are putting this product, this nail polish remover on your nails and then you wash it off and then it goes into the water supply. Nobody seems concerned about it. Why? Nobody is regulating it. Why? Because nobody real, in the scientific industry, thinks it is a problem.

And if you are grown up and you are saying well, you know, I am taking good care of my nails; I probably don't bite them if I am--another product, and I didn't want to bore you by filling the shelf with household items here, but you could just go down and read the labels and find out what you have in every store that you go into. This is something that we put on the nails of our children and our grandchildren to prevent them from biting their nails. Why? Because it has a bittering agent. What is the bittering agent? Why, it is DB.

Now, why would you put this on the nails of a child that you love if you are going to be poisoning him? And the answer is he doesn't get poisoned. He is putting it in his mouth. Well, if he is playing in the driveway or in the garage and he puts his hand on the floor, it is not the DB that we are worried about, because we are already using it in just about half the things that we use, but it is the antifreeze. That is the problem.

Let me address the two issues that I have heard people express as concerns, and the answers really are in the bill, if you read the bill carefully and it is not a very long bill. Liability. I don't want anybody to be off the hook. If you are responsible for something dangerous, then you are responsible to the fullest extent of the law. But the gentleman is right. If you are going to require somebody to put their product in your product, you should be responsible for your product; they should be responsible for their product. The bill specifically says that. The antifreeze manufacturers are answerable in every single way under the bill; it is on page 3 under Limitation of Liability, that if you are required to put the DB in your antifreeze, you are responsible for everything that you voluntarily put in the antifreeze, environmentally and health-wise.

And right, that is on line one. If you go down to line two, it says you are not being left off the hook. If you go to paragraph three, it says that nothing in this bill is construed to keep the manufacturer of DB on that slippery slope we are worried about. If you made the DB and there is a problem with DB to the environment or to somebody's health, you are responsible for that. Manufacturer A is responsible for A; Manufacturer B is responsible for B. If we require A to be inserted in B, that is our demand. And the people who are making these things are responsible. Nobody gets off the hook.

Preemption. And by the way, I didn't mention it, the issue of effectiveness arose. This is the stuff that they put, those of you who are fortunate enough to live in areas where there are deer and animals, et cetera, this is the stuff that we put DB in the spray on the trunks of our trees and on our foliage to keep the deer from eating it. Seems to me that

washes into our soil pretty quick, as soon as it rains and into our aquifers and water supplies. We don't worry about that. Why? Because evidently, there is nothing to worry about.

The second issue that people brought up as a concern was preemption, and I am as interested in preemption as anybody else. But States are beginning to act because they are ahead of us in understanding the danger both to animals that we all profess to love and our children that I know we all love, and the environment that everybody talks so much about. States are beginning to act. Three States have done it, eight more States are considering it. If every State had different regulations you are not going to have manufacturers of anything making 50 different products in 50 different States.

And besides, even if they did, or even if those three States did, what is to prevent this mean New Yorker from driving my mean New York car with my terrible antifreeze in it, without a bittering agent into your State in California? Are we going to stop every car from every State from coming into the three States or whatever amount of States it amounts to and make you sign an affidavit that there is no DB because your car is going to leak if it is going to leak. And if you think they don't, walk through the parking garage in any of our buildings or the parking lots outside where all the staff cars are and just look at the ground and see all these liquids there.

It is a problem and it is a mobile problem and being that mobile in every way. And if we are talking about motor vehicles that go around the country, maybe less because of the price of gas, but how do you stop this, in one State there is no protection? And the real answer is there should be one standard. And if there is one standard that everybody sticks to, as long as we can agree on it, and by the way, this isn't a boon to any one company. You know the amount of this that it would take annually, is 7,000 gallons, total. This isn't MTBE where you are talking about 82 billion gallons of gasoline stored in cans that are underground that are going to leak. This isn't that material. This is something completely different.

So I just urge my colleagues, and this has been very confusing and it has to do with chemistry and I was never good at chemistry, but I am starting to learn a little bit now that I am watching it a little bit more closely with respect to this. This is easy to figure out. This is cheap. It is a heck of a lot cheaper than the pain and anguish to 14,000 mothers and 14,000 fathers and 56,000 grandparents mourning over the poisoning of a child. And if we are talking about up to 90,000 dogs and cats, some are strangers, some are family members to a lot of people, over 10 years, that is 900,000 pets. This is something that we can do something about. And if we are worried, let us rush to ban all of these household items that everybody uses. I thank you for your attention.

### [The prepared statement of Hon. Gary L. Ackerman follows:]

# PREPARED STATEMENT OF GARY L. ACKERMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Good afternoon. I want to thank Chairman Gillmor and Ranking Member Solis for holding this important hearing and allowing me to testify before the subcommittee.

I'm here for one simple reason: 1,400 children are poisoned by antifreeze every year. In addition between 10,000 and 90,000 dogs and cats are poisoned by antifreeze ingestion each year. A mere sip or lick of antifreeze can result in agonizing kidney failure, respiratory arrest, comas, and death.

That is why this bill is so important. Unless Congress acts, thousands more children and tens of thousands more household pets will unnecessarily suffer horribly, or even die. We can prevent all of this suffering for no more than 3 pennies per gallon.

We all know that cars sometimes leak fluids, including antifreeze, which can puddle up in driveways, along curbsides, and in parking lots. Animals are all too eager to lap up these sweet-tasting puddles, and children playing outdoors can easily come into contact with these puddles and then place their hands in their mouths. In fact, the sweet taste of antifreeze may cause these unsuspecting children to return for more of the deadly substance. Moreover, dogs have been known to chew the necks of antifreeze containers, and curious children may come across the bright colored, sweet tasting substance in a garage and mistake it for a juice-drink or other safe beverage. I ask all of you, can you tell me which of these glasses contain the safe drinks and which one is filled with toxic antifreeze?

Antifreeze has also become the weapon of choice for intentionally poisoning people as well as pets. Its sweet taste makes it all too easy to mix into a deadly cocktail for an unsuspecting guest or neighborhood pet.

The Antifreeze Bittering Act would prevent all of these tragedies by requiring the world's bitterest known substance, *denatonium benzoate* – which, for ease of use, I will refer to as DB from now on – to be added to antifreeze in order to make it unpalatable. According to antifreeze producers, the process would be simple to implement and cost only two to three pennies per gallon.

For once, we have a simple solution for a very grave problem, and it has a lot of support. The Antifreeze Bittering Act has 61 bipartisan cosponsors and has been endorsed by the American Academy of Pediatrics, the American Veterinary Medical Association, Doris Day Animal League, The Humane Society of the United States, Pfizer Animal Health, the Society for Animal Protective Legislation, the American Humane Association, the Pet Food Institute, the Long Island Pine Barrens Society, Consumer Specialty Products Association (who represent the antifreeze industry), and Honeywell (the leading manufacturer of antifreeze).

Moreover, the American Medical Association, the American Association of Poison Control Centers, the National Safety Council, and the American Journal of Public Health all publicly urged the addition of an aversive agent to antifreeze. The U.S. Conference of Mayors passed a resolution in 2004 urging Congress to "help cities protect children and animals" by passing a bill to require the addition of DB to antifreeze. And, three states – Oregon, California, and New Mexico – have already adopted their own laws requiring the addition of a bittering agent to antifreeze, while eight others – Maine, Massachusetts, Nebraska, Nevada, New York, New Jersey, Tennessee, and Washington – currently have legislation pending.

Given this unique combination of supporters – animal activists agreeing with the industry, pediatricians and veterinarians are on the same page as drug manufacturers, republicans standing with democrats – this bill should be headed for the suspension calendar. Nevertheless, I do understand that there are some concerns about the bill's language, and I am hopeful that we can work through these differences together.

There is a misunderstanding that the Antifreeze Bittering Act would set a dangerous precedent regarding environmental liability waivers because they think the bill contains broad liability waivers that could undermine the "polluter pays" principle. This is simply not the case – there are no blanket liability exemptions. Instead, the bill contains a tightly drafted provision that establishes assigned liability for the antifreeze and DB industries. Since the legislation would require the antifreeze industry to add a substance to their product, a substance that they do not produce, the language makes it clear that each industry is to be held liable for their own product: the antifreeze industry will be liable for antifreeze and the DB industry will be liable for DB. No one gets off the hook. There is absolutely no gap in corporate liability and there are no loopholes.

I also understand that some of you are concerned about the environmental fate of DB. DB was first approved for use in the United States in the 1960s, and has been used for decades as a bittering agent in hundreds of household cleaning products, cosmetics and personal care products, detergents, drain cleaners, paint, pesticides, and even outdoor garden sprays.

To date, DB has demonstrated no significant environmental hazards, whether disposed of properly or not, and will not enter the drinking water supply. An analysis by the California Integrated Waste Management Board found that DB "readily biodegrades, its transport is attenuated [or withheld] by soil, and it is easily treated in sewage treatment systems and drinking water systems. The analysis also "determined that the addition of [DB] to antifreeze would not lead to any adverse health or environmental effects." And, even if all of the DB analysis turns out to be inaccurate or incomplete, the DB industry remains liable for their product.

We must also remember that ethylene glycol antifreeze is already considered a hazardous substance. The EPA warns that dumping antifreeze can cause serious water quality problems, as used antifreeze contains lead, cadmium, and other heavy metals. As a result, the industry urges consumers to properly dispose of used antifreeze, and the addition of DB to antifreeze will certainly not change this fact.

It's also important to keep in mind that we are talking about minute amounts of DB. It is estimated that only 7,000 gallons of DB can bitter all of the approximately 157 million gallons of antifreeze covered by the legislation. Let me repeat that -7,000 gallons of DB for 158 *million* gallons of antifreeze. To help put that into perspective, we are talking about 1-2 droplets of DB for this 1 gallon container of antifreeze.

There is also a growing need for Congress to address this issue. As I mentioned earlier, states, cities, and even municipalities have already begun the process of enacting their own antifreeze bittering laws. Since antifreeze is sold throughout the entire country, there is an obvious need for one single federal standard.

It is my sincere hope that this hearing will help to clear up some of the misunderstandings surrounding the Antifreeze Bittering Act, and that we can act quickly to prevent further poisonings of children, household pets, and other unsuspecting victims who suffer needlessly because they have unintentionally ingested antifreeze.

MR. GILLMOR. Thank you, Mr. Ackerman. Questions? Any questions for Mr. Ackerman? If not, thank you very much for being here.

MR. ACKERMAN. I will take this from the table and if anybody wants, the drinks are on me later.

MR. GILLMOR. I call our second panelist. Just don't drink anything that was left there. I ask Jim Willis, the Division Director of the Chemical Control Division, Office of Pollution Prevention and Toxic Substances of U.S. EPA to come forward. Mr. Willis, whenever you are ready.

## STATEMENT OF JIM WILLIS, DIVISION DIRECTOR, CHEMICAL CONTROL DIVISION, OFFICE OF POLLUTION PREVENTION AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY

MR. WILLIS. Thank you. Chairman Gillmor, Ranking Member Solis, members of the committee, thank you for your invitation to appear before you today. I am Jim Willis. I am director of EPA's Chemical Control Division and it is my division that is responsible for managing EPA's processes for reviewing new and existing chemicals and taking action, if appropriate, under the Toxic Substances Control Act, TSCA. With your kind permission, I would be grateful if my written testimony could be included in the record of today's meeting.

MR. GILLMOR. Without objection.

MR. WILLIS. Thank you. It is my privilege to represent EPA during this discussion on the bittering agent denatonium benzoate or DB for short. The bill under consideration, H.R. 2567, would mandate the addition of this bittering agent to engine coolant or antifreeze that contains more than 10 percent ethylene glycol. At the present time, the Administration does not have a position on this bill. I would like to give the subcommittee a summary of our findings concerning the risks of DB. This is, of course, preliminary in nature and we are pleased to update this as new data become available. The agency has collected information and performed a screening level analysis of DB. We have not conducted a full risk assessment.

There is not an extensive database of toxicity or environmental fate information on DB, although there is a 2 year oral toxicity study in rats and several other oral studies in rats of shorter duration. Using the available information, the agency has applied screening level toxicity and environmental exposure estimation techniques that are often used in assessments of industrial chemicals prior to entry into commerce pursuant to TSCA. These analyses typically employ techniques where toxicity and exposure values are estimated from structurally similar compounds. We use computer-based models or expert judgment where toxicity or environmental exposure values are predicted based on a chemical structure. I am pleased to share with the committee an overview of this analysis, although I would like to repeat my earlier caveat that this is not exhaustive. Concerning possible environmental exposure, based on the chemical structure, DB is predicted to be water soluble. We also predict that the chemical may readily move from water and adhere to soil or sediment. It is not predicted to bio-accumulate in living organisms. In addition, the chemical is not predicted to be volatile, so it would not be expected to move from water into the atmosphere.

The chemical is predicted to be resistant to biodegradation. So for example, if DB were released into a sanitary sewer system, it most likely would be removed in a sewage treatment plant through absorption to sludge and not through appreciable biodegradation. If DB were released directly to surface waters, we would expect it to accumulate in sediments due to its predicted tendency to move from water and adhere to soil and its resistance to biodegradation. The chemical would not be predicted to readily migrate to groundwater because of this same tendency. With sandy soils, however, potential movement to groundwater would be greater than for soil-rich organic matter.

Concerning possible human and wildlife exposure, we would note that DB is one of the most bitter and bad tasting chemicals known. Consequently, it is at times used as a minor ingredient in a number of consumer products, which was amply demonstrated earlier, to deter human ingestion. Because of this human aversion to DB, oral exposure potential for humans is therefore expected to be low. Other mammals are likely also adverse to DB. If orally consumed, data on these structurally similar chemicals leads us to believe DB would not be readily absorbed into the gastrointestinal tract and not likely to be efficiently absorbed through the skin.

With regards to toxicity, our evaluation indicates that there were no appreciable concerns identified for mutagenicity, carcinogenicity or developmental toxicity from this chemical. Overall, given the limited database and the uncertainties thereby presented, it is predicted that there is low to moderate concern for toxicity to humans and mammalian wildlife. Please note that this low to moderate ranking is, indeed, the lowest ranking of health concern that we give during our screening level analyses.

We also predict that DB is not likely to be highly toxic to birds. We predict that DB is likely to be, at most, moderately toxic to aquatic organisms and plants, with fish, aquatic invertebrates, and algae being least to most sensitive, respectively. The toxicity to aquatic species is predicted to be reduced, again, to the extent that soils or sediments are present in the water and the DB adheres to them.

In summary, on the basis of our screening level analysis, DB would not be expected to pose a significant risk to human health or the environment. While the information presented is limited and should not be construed as an exhaustive assessment, I hope it is nonetheless useful to the committee as you consider this issue. Thank you for the opportunity to testify today. I would be pleased to answer any questions.

[The prepared statement of Jim Willis follows:]

### PREPARED STATEMENT OF JIM WILLIS, DIVISION DIRECTOR, CHEMICAL CONTROL DIVISION, OFFICE OF POLLUTION PREVENTION AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY

### I. Introduction

Mr. Chairman and Members of the Committee, thank you for the invitation to appear before you today. It is my privilege to represent the U.S. Environmental Protection Agency during this discussion on the bittering agent denatonium benzoate. The bill under consideration, H.R.2567, would mandate the addition of this bittering agent to engine coolant or antifreeze that contains more than 10 percent ethylene glycol. At the present time, the Administration does not have a position on this bill.

### **II.Background**

The Agency has collected limited information and performed some screening-level analyses on denatonium benzoate; however, we have not conducted a full risk assessment, nor is there available an extensive database of toxicity or environmental fate information on denatonium benzoate. Using the available information, the Agency has applied screening-level toxicity and environmental exposure estimation techniques that are often used in assessments of industrial chemicals prior to entry into commerce pursuant to the Toxic Substances Control Act (TSCA).

These analyses typically employ techniques where toxicity and exposure values are estimated from structurally similar compounds, using computer-based models or expert judgment, where toxicity or environmental exposure values are predicted based on a chemical's structure. These analyses do not currently provide enough information for the Agency to conduct a thorough human health or environmental assessment on this chemical. As such, the Agency's analyses on denatonium benzoate should not be construed to be an Agency position on the health and safety of denatonium benzoate. There simply is not enough information available at this time to make such a finding. Nonetheless, I am pleased to share with the Committee the results of the Agency's screening-level analyses on the exposure and toxicity information that we have developed by employing the modeling techniques mentioned above.

### **III.** Environmental Exposure

Based on the chemical's structure, denatonium benzoate is predicted to be water soluble; however, it is predicted that the chemical may readily move from water and adhere to soil or sediment. It is not predicted to bioaccumulate in living organisms. In addition, the chemical is not predicted to be volatile, so it would not be expected to move from water to the atmosphere. The chemical is predicted to be resistant to biodegradation. For example, if denatonium benzoate were to be released into a sanitary sewer system, it most likely would be removed in a sewage treatment plant through adsorption to sludge and not through appreciable biodegradation. If denatonium benzoate were released directly to surface waters, it would be expected to accumulate in sediments due to its predicted propensity to move from water and adhere to soil, and its resistance to biodegradation. The chemical would not be predicted to readily migrate to groundwater because of its propensity to adsorb to soil; however, with sandy soils, potential movement to groundwater would be greater than if applied to soil rich in organic matter.

### IV. Human/Wildlife Exposure

Denatonium benzoate is one of the most bitter and bad tasting chemical substances known. Consequently, it is at times used as a minor ingredient in consumer products, such as denatured alcohol, to deter human ingestion. Because of human aversion to denatonium benzoate, oral exposure potential for humans is expected to be low. Other mammals are likely also averse to denatonium benzoate. If orally consumed, data on structurally similar chemicals leads us to believe it would not be readily absorbed in the gastrointestinal tract and not likely to be efficiently absorbed across the skin.

### V. Human/Wildlife Toxicity

Our preliminary evaluation indicated there were no appreciable concerns identified for mutagenicity, carcinogenicity, or developmental toxicity from this chemical. Overall, given the limited data base, and the uncertainties thereby presented, it is predicted that there is low to moderate concern for toxicity to humans and mammalian wildlife and that the chemical is not likely to be highly toxic to birds.

### VI. Aquatic Toxicity

Again, based on the models and the Agency's screening-level analyses, the compound is predicted to be moderately toxic to aquatic organisms and plants, with fish, aquatic invertebrates, and algae being least to most sensitive, respectively. The toxicity to fish, aquatic invertebrates, algae and aquatic plants in the water column is predicted to be reduced to the extent that soils or sediments are present in the water, again, because of the chemical's propensity to adhere to these materials.

### V. Conclusion

Thank you for the opportunity to provide you with this information. While the information presented is limited and should not be construed as an Agency position on the health and safety of denatonium benzoate, I hope the information nonetheless is useful to the Committee as you consider this issue. I will be pleased to answer any questions.

MR. GILLMOR. Thank you very much, Mr. Willis. The testimony of our first witness, Congressman Ackerman, talked about DB being in a myriad of products commonly used, everything from Q-tips to being sprayed on trees. Would you agree with that, that it is a very common substance in a number of products?

MR. WILLIS. Yes, I would agree that it is commonly found.

MR. GILLMOR. Are you aware of any problems as a result of that widespread use?

MR. WILLIS. Well, we have not done an exhaustive search of whether there are reported problems, but in the areas where we have looked, we have not heard any reports of problems.

MR. GILLMOR. Title II of the Consumer Product Safety Improvement Act of 1990 mandates a study of the effectiveness of adversive agents in deterring ingestion of hazardous products. Are you familiar with that study? MR. WILLIS. Unfortunately, Mr. Chairman, I am not familiar with that study.

MR. GILLMOR. Okay. Let me ask you about the environmental effects of plain antifreeze, forget bittering agents, plain antifreeze being released into soil and water. Would it be possible to have a bittered antifreeze released into the environment and then have the only environmental damage come from the antifreeze and not from the bitterant?

MR. WILLIS. Thank you for that question, Mr. Chairman. The environmental effects of plain antifreeze being released into the environment are low. Plain antifreeze has a very low toxicity and is easily biodegradable, so it is not persistent in the environment. The environmental damage caused by the bittering agent, if added to antifreeze and released with antifreeze, is also expected to be low. It has a low toxicity to fish and aquatic invertebrates. It does have moderate toxicity to green algae, but green algae recovers relatively quickly to threats and so this is not anticipated to be a serious problem. And once the part of the chemical of concern is absorbed to soil, that toxicity would also be reduced.

MR. GILLMOR. Thank you. Further questions of the witness? Ms. Solis.

MS. SOLIS. Thank you. Mr. Willis, thank you for being here and your presentation. I wanted to ask you if EPA has done any actual analysis of the measured toxicity, values, or environmental fate in transport of bitrex?

MR. WILLIS. No, Congresswoman Solis, we have not actually done any testing ourselves. We have reviewed available data that has been made known to us. We have also reviewed two structurally very similar chemicals and looked at the data associated with them and a number of other analogs, but we have not done any testing ourselves.

MS. SOLIS. Okay. Mr. Willis, to your knowledge, has Honeywell or their trade association, the Consumer Specialty Products Association, provided you with scientific studies they have accumulated which show that DB does not biodegrade in the environment or presents risks in the groundwater?

MR. WILLIS. I am not aware of that, no.

MS. SOLIS. And are you aware of a study done by a consulting firm known as Roy F. Weston that concluded that DB does not biodegrade and would pass through publicly owned treatment works?

MR. WILLIS. I am not aware of that study, no.

MS. SOLIS. Are you aware of another study done by Roy F. Weston that reached the conclusion that if you put DB down the drain, it goes right into the water and does not biodegrade?

MR. WILLIS. No, I have not looked at any of these studies myself.

MS. SOLIS. Okay. And are you aware of another study performed by the Chemical Specialties Manufacturers Association which concluded that DB does not stick in the soil, rather it stays in and travels with the groundwater, therefore it is reasonable to expect contamination problems. As the DB accumulates in the groundwater, the net result is that the groundwater may become bitter and thus, well water in the area would potentially be unpotable?

MR. WILLIS. No, I am not familiar with that.

MS. SOLIS. Since there are numerous studies that show DB does not biodegrade, is it likely not safe for the environment? Is the EPA supporting the sweeping liability exemption from the Superfund and other environmental laws as contained in H.R. 2567?

MR. WILLIS. Congresswoman, as I noted in my testimony, the Administration doesn't actually have a position on this bill and that would include on the liability provision.

MS. SOLIS. And has EPA attempted to get environmental fate and transport data from the manufacturers of this product?

MR. WILLIS. No, Congresswoman. We have just performed the inhouse screening level analysis based on data that was readily available.

MS. SOLIS. So does that exclude sound scientific studies?

MR. WILLIS. It would not exclude sound scientific studies, no. It would be based on any data that were available to us. We did not do a data call-in, for example, to get data from manufacturers and others who may have tested this, but relied on readily available information.

MS. SOLIS. Thank you. I would also like to ask for unanimous consent to submit correspondence that we have received in the committee to be added to the record and hopefully allow for other materials that Members might have to bring forward to put in the record.

MR. GILLMOR. Would the gentlelady have any objection to giving Members a couple of days as part of the unanimous consent to submit, as part of the record, any rebuttal materials, as well, so that both sides of the issue are in the record? Okay. Then, without objection, the unanimous consent request as amended is agreed to.

[The information follows:]

OF: -- 11 PO Box 509 Beacon NY 12508 914 838 7294 914 838 7105 FAX Mary Jane Von Allmen Texaco In Manager Product Salety Texaco's data on degradation stadies in fleets & animals August 26, 1991 4 ADVERSIVES ges away in the cars & mals are not adverse Office of the Secretary Consumer Product Safety Commission Washington, DC 20207 toit

Dear Sir/Madam:

In response to your request (<u>Federal Register 56</u> (126) July 1, 1991) regarding the use of aversive agents in consumer products, Texaco is providing you with the following document summarizing our research on the aversive agent BITREX in antifreeze.

To establish the efficacy of aversive agents in antifreeze, animal studies using beagle dogs were used to quantify any potential aversive properties imparted to the antifreeze by the aversive agent BITREX. Analytical determinations on antifreeze containing known concentrations of BITREX under actual conditions of use (Texaco 'fleet cars') were also conducted. The results of the animal studies, sponsored by Texaco Chemical Company, indicate that BITREX did not impart any aversive properties to antifreeze. On a closer examination of the data, it became apparent the antifreeze itself was, in fact, unpalatable to dogs. This finding casts doubt on the "central premise" of antifreeze may be affected by factors other than taste, especially an excessive degree of thirst, and possibly "individual preferences." Analytical determinations, conducted by Austin Research Labs, on samples of antifreeze taken from fleet cars indicate that BITREX is not stable in automotive cooling systems.

Texaco would be pleased to provide any additional information if needed.

Sincerely,

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Attachment

### AVERSIVE AGENTS

### **EFFICACY INVESTIGATIONS**

To establish the efficacy of aversive agents in antifreeze, a program was proposed in 1989 to investigate three aspects of the efficacy of aversive agents: animal aversion studies (taste preference studies) to establish the possibility of "pet proofing" antifreeze solutions; the stability of the aversive agent under conditions of use in automobiles; and adult and child taste panels, to establish the efficacy of aversive agent to human poisoning situations. However, at that time, due to ethical and legal considerations, the use of adult and child taste panels were not considered for further study. Efforts at determining the efficacy of BITREX were therefore limited to the animal studies and the analytical determinations. Due to the willingness of Macfarlan Smith to participate in our studies, BITREX was selected as the "representative" denaturing agent to be used in our studies.

### ANIMAL DATA

There have been two studies that have, either directly or indirectly, investigated the efficacy of BITREX in antifreeze. Texaco has conducted animal studies at Pharmakon Research International, a contract testing facility, located in Waverly, PA. These studies were funded through the sponsorship of Texaco Chemical Company. The second study, although not investigating the efficacy of aversive agents in antifreeze, provided necessary supporting evidence for the data resulting from the Texaco study. This supporting study was conducted by two researchers at the University of Pennsylvania, David Marshall, and

-1-

Richard Doty.

The Texaco study, originally examined the use of BITREX at 25 ppm in propylene glycol solution (50% in water). Propylene glycol was selected as a non-toxic alternative for the ethylene glycol component of antifreeze. It was "Common Knowledge" that both materials tasted similar. Results from the preliminary studies demonstrated that BITREX in propylene glycol was not effective as a denaturing agent, the animals ingested neither propylene glycol, or propylene glycol with BITREX. Average water intake (over the 8 hour testing interval) for beagle dogs of this age and weight range is approximately 250 to 350 mls. To resolve the lack of ingestion of the propylene glycol, previously thought to be "sweet tasting", human taste tests with volunteers were conducted. This test demonstrated that propylene glycol was quite bitter, and was probably aversive to the animals even without BITREX added. (Table 1.) To assure that BITREX was indeed aversive, BITREX was mixed in water at 25 ppm, and a choice was given between water and water/BITREX. The results of this study demonstrated that BITREX imparted aversive properties to the water, reflected in the reduced consumption of the water and BITREX sample. As a follow-up to this study, dogs were given a choice between water and undiluted antifreeze with BITREX, and consumption was almost exclusively of the water sample. (Table 2.)

Based on the poor results of the above study, it was decided that antifreeze should be used as the test solution. Following Macfarlan Smith's recommendations for appropriate concentrations of BITREX in glycols, BITREX was added to the diluted (50% in water) antifreeze solution at the initial concentration of 25 ppm. Water would be provided as a

- 2 -

comparison fluid. Water bottles were covered to prevent the dogs from forming an association between color and aversive taste, and the positions of the bottles on the cages were randomly selected to prevent the dogs forming an association between location of the water bottle and an aversive taste. At 25 ppm BITREX in antifreeze, relative fluid consumption demonstrated that water was the preferred fluid for ingestion, little of the BITREX in antifreeze solution was ingested. Subsequent testing, halving the concentration of BITREX in antifreeze on a weekly basis, convincingly demonstrated that BITREX was imparting an aversive taste to the antifreeze/BITREX solution. Water consumption was always much higher than the antifreeze/BITREX fluid. At the last trial of this study, the concentration of BITREX in antifreeze was lowered to a 3.5 ppm, and aversive properties of this solution were apparently still evident. (Table 3.)

While the data generated in the above study was very good, the study design was confounded by the fact that due to the inherent toxicity of antifreeze solutions, the dogs were never given a choice of "antifreeze alone." (If the dogs had ingested any of the antifreeze solutions, it would have been necessary to "destroy" the dog to prevent a painful death from the ethylene glycol poisoning.) The "antifreeze alone" group would have been a suitable control group for the antifreeze/BITREX fluids. Therefore, while the aversive properties of the antifreeze and BITREX solutions were thought to be attributable to the aversive properties of BITREX alone, a rigorous and complete test was not conducted. The data were suspect in one other way, as well. Based on Macfarlan Smith's recommended BITREX concentration of 25 ppm, the results at 3.5 ppm were certainly unexpected. Neither they, or Texaco expected much aversive taste in glycols at 3.5 ppm.

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To assist in the interpretation of the above studies, and examine the aversive properties of antifreeze, a new study was performed with a smaller number of dogs (to prevent a large problem with EG poisoning) never having experienced the taste of antifreeze, and given the choice between diluted antifreeze and water solutions. The results were quite unexpected, the dogs preferentially drank water; antifreeze, by itself, was apparently aversive to the dogs. To complete our investigations, the dogs were given a choice between diluted antifreeze containing BITREX at 25 ppm. The outcome of this study was equally surprising, the animals ingested neither solution, but were quite content to "wait it out," drinking a minimum of these solutions during the testing interval. (Table 4.) Although the data is not shown, an additional study was conducted as outlined above, but using a different antifreeze formulation, and the results were similar to those with our original formulation.

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The results of our study can be summarized as follows:

- 1) Propylene glycol, with or without BITREX, is unpalatable to dogs.
- 2) BITREX in water is aversive to dogs.
- 3) Antifreeze is unpalatable to dogs, with or without BITREX.
- 4) Given a choice between water and antifreeze, water is preferred.
- 5) Given a choice between antifreeze and antifreeze with BITREX, neither is ingested.
- 6) Antifreeze is unpalatable to dogs, even without the addition of BITREX.
- 7) WE HAVE FOUND NO EVIDENCE TO DATE THAT BITREX IMPARTS ANY AVERSIVE PROPERTIES TO ANTIFREEZE, REGARDLESS OF COMPOSITION.

The supporting study conducted by Marshall and Doty at the University of Pennsylvania,

- 4 -

examined the taste preferences of dogs to water, 20% sucrose, 50% ethylene glycol, 50% propylene glycol, and 50% antifreeze solutions, under several water deprivation regimens. Their data (Table 5.) demonstrates that the preference (in highest to lowest) order of ingestion for these solutions was: sucrose > water > ethylene glycol > antifreeze = propylene glycol.

The Texaco data, taken in conjunction with the Marshall and Doty data, seem to indicate that the "Central Premise" of antifreeze poisonings is incorrect: Dogs DO NOT find antifreeze to be attractive by taste. Ingestion of antifreeze may be affected by factors other than taste, especially an excessive degree of thirst, and possibly "individual preferences."

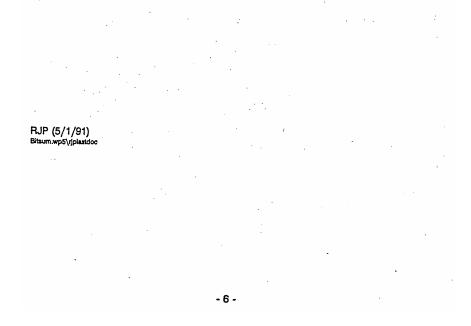
### ANALYTICAL DATA

Analytical data on the stability of BITREX in antifreeze was conducted through a cooperative effort between Texaco's Beacon Research Lab (fleet cars) and Texaco Chemical Company's Austin Research Labs. Preliminary indications have shown that BITREX in antifreeze is not stable in automotive cooling systems, regardless of mileage. Other studies on the stability of BITREX, conducted by BASF, have indicated a "near complete" degradation of BITREX in antifreeze over a 5 month interval in "oven tests" presumed to approximate the temperature of automotive cooling systems. These results indicate that BITREX would not impart any aversive qualities to "used" antifreeze. Neither Texaco, BASF, or Macfarlan Smith, have investigated the aversive properties, if any, of the breakdown products of BITREX.

## SUMMARY AND RECOMMENDATIONS

The results of this project investigating the aversive properties of BITREX in antifreeze can be summarized as follows:

- 1) TEXACO HAS FOUND NO EVIDENCE TO DATE THAT BITREX IMPARTS ANY AVERSIVE PROPERTIES TO ANTIFREEZE, REGARDLESS OF COMPOSITION.
- 2) Data generated by Texaco and by Marshall and Doty have indicated that the "Central Premise" of antifreeze poisoning may be incorrect, antifreeze MAY NOT be attractive to animals.
- Analytical data, from Texaco and BASF, indicate that BITREX is not stable in test fleet cars, and would not be expected to confer long-term aversive properties to antifreeze used in automobiles.



## AVERSION STUDY #1 USING BITREX IN ANTIFREEZE - BEAGLE DOGS Fluid consumption data in milliliters (mls)

25 ppm BITREX (B) in Propylene Glycol (PG) Solution (50%) 8 hour water deprivation prior to 6 hour consumption

Dog	DAY 1		{	DAY	2			DAY :	3
#	PG	PG+B		PG	P	G+B		PG	PG+B
1 2 3 4 5 6 7 8 9 10	40 0 20 0 20 0 20 0 10 40	20 40 20 20 20 180 20 60 60		40 0 20 40 20 80 40 40 40		80 20 20 20 20 60 0 20 60		20 0 40 20 0 120 40 140 40	0 0 0 0 100 20 120 20
AVG =	13	46		38		30		42	26
Dog #	DAY 4 PG	PG+B			5	•			
1 2 3 4 5 6 7 8 9 10	60 - 20 20 20 20 20 80 20 60 40	100 0 20 0 120 20 20			••• • •			•	
$\lambda VG =$		28		•			•		•
			- 1	8 <b>-</b>					

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## AVERSION STUDY #1 USING BITREX IN ANTIFREEZE - BEAGLE DOGS Fluid consumption data in milliliters (mls)

## 25 ppm BITREX (B) in Water (W) 6 hour consumption

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1		No depriv	ation	1	18-24 hr depriv.
Dog	DAY 1		DAY 2		DAY 3
+	W	W+B	W	W+B	W W+B
1	190	60	260	50	
2	20	0	10	0	
3	220	0	0	o l	1
4	20	200	160	ŏ	Data collected
5	0	100	280	· o	but not
6	0	40	180	ŏl	tabulated
7	260	100	260	ŏ	Cabaracea
8	20	60	220	ŏÌ	
9	220	0	160	20	
10	180	0	180	80	
λVG =	113	56	171	15	** ** ** ** ** ** ** ** ** ** ** ** **

## 25 ppm BITREX (B) in Undiluted Antifreeze (UAF) 8 Hour consumption

Dog	DAY	1	DAY 2
1	W	UAF+B	W UAF+B
1	900	40	
.2	80	10	
3	450	20	· .
4	950	40	Data collected
5	300	0	but not
6	20	0	tabulated
7	660	60	· · · · ·
8	200	20	•
9	320	20	
10	680	30	
VG =	456	24	

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## AVERSION STUDY #1 USING BITREX IN ANTIFREEZE - BEAGLE DOGS Fluid consumption data in milliliters (mls)

## 25 ppm BITREX (B) in Antifreeze (AF) Solution (50%) 8 hour consumption

Dog	DAY 1	L	DAY	2	DAY :	3
1	W	AF+B	W	AF+B	W	AF+B
1	800	0	520	20	500	20
2	30	0	0	0	20	40
3	480	0	140	40	380	20
4	80	.0	120	0	0	40
5	80	40	0	20	200	20
	140	0	200	0	100	0
. 7.	420	0	380	20	600	.40
8	420	10	. 220	20	0	20
9	460	20	640	20	320	40
10	440	• 0	320	20	420	20
AVG =	335	7	254	16	254	26

# 12.5 ppm BITREX (B) in Antifreeze (AF) Solution (50%) 8 hour consumption

Dog	. DAY 1	- 1	DAY	2	DAY :	3 ·
1	W	AF+B	W	AF+B	W .	λF+B
1	520	20	400	20	520	0
2	0	20	- 20	20	160	ő
3	280	40	200	20	20	40
4	440	20	40	20	160	80
5	20	60	80	20	140	20
6	20	20	40	.0	. 0	20
7	500	40	480	40	260	40
8	20	40	100	20	300	20
9	340	20	400	40	420	60
10	520	60	380	20	280	20
AVG =	266	34	214	22	226	30

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### TABLE 3 Cont.

# AVERSION STUDY #1 USING BITREX IN ANTIFREEZE - BEAGLE DOGS Fluid consumption data in milliliters (mls)

# 7.5 ppm BITREX (B) in Antifreeze (AF) Solution (50%) 8 hour consumption

•	DAY 1	L J	DAY 2	· · · · · ·	DAY 3	
Dog #	∕ ₩	AF+B	W	AF+B	W	AF+B
1	580	20	480	0	560.	0
2	20	30	260	. 0	20	0
3	180	0	240	40	120	20
4	120	20	100	30	360	30
5	20	20	20	0	20	40
6	130	20	40	20	110	· 0
7	600	20	320	0	410	. 20
8	60	10	180	0	530	20
ÿ.	340	40	320	20	490	20
10	500	0	420	Ö	500	0
AVG =	255	18	238	11	312	15

# 3.5 ppm BITREX (B) in Antifreeze (AF) Solution (50%) 8 hour consumption

1	DAY 1	L [	DAY 2	2	DAY :	3
Dog #	W	AF+B	W	AF+B	W	λF+B
1	480	40	520	20	600	20
2	40	20	0	· 0	120	20
3	320	40	· 260	0	200	40
4	280	40	220	0	280	40
	100	0	40	0	160	20
5	20		140	0	180	0
7	480	20	480	40	560	40
8	180	o	380	40	260	20
9	340	30	400	40	400	20
10	500	20	620	0	620	0
AVG =	274	21	· 306	14	338	22

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STUDY NOTES: 1 - Animals 1 through 5 are males, 6 through 10 àre females. 2 - Water deprivation prior to periods of consumption was only for the runs indicated. - 11 -

- 11 -

# AVERSION STUDY #1 USING BITREX IN ANTIFREEZE - BEAGLE DOGS Fluid consumption data in milliliters (mls)

## (Naive animals never experiencing antifreeze)

# Antifreeze (AF) Solution (50%) 8 hour consumption

Dog	DAY 1	L	DAY 2	1	DAY 3	1
#		λF	W	λF	W	λF
1 2 3 4	20 600 40 640	30 20 40 20	0 680 40 280	20 40 20 60	40 420 160 480	40 60 40 40
AVG =	325	27.5	250	35	275	45

# 25 ppm BITREX (B) in Antifreeze (AF) Solution (50%) 8 hour consumption (AF controls)

Dog	DAY	L · ·	DAY :	2	DAY 3	3
1	λf	AF+B	λf	AF+B	AF	AF+B
1 2	40 40	30 40	20 40	20 0	40 60	40 40
3 4 	40 100	20 40	40	20 0	20 60	20 20
λVG =	55	32.5	35	10	45	30

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STUDY NOTES:
1 - Above animals are "naive", never experiencing antifreeze. These animals serve as a check for acclimation to color/odor and taste of BITREX in the main group of study animals.
2 - Water deprivation prior to periods of consumption was only for the runs indicated.

- 12 -

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•				• .•			
					Test solytion	E	
<b>Deprivation condition</b>	Dag No.		Water	Sucrose	EQ	PG	AF
	-		1,016	1,316	12 .		0
-	2		83	664	12	0	.0
No deprivation	<b>3</b>		204	744	97	.,	27
	4		314	533	17	7	18
	ى ي		313	1,369	10	0	<b>0</b>
- -	-	•	337	1,263	2	121	33
•	2		412	809	 2.	0	0
19-h deprivation	ί.		32	606	5	9	14
	4		563	721	113	4	24
	ß		1,163	1,804	427	<b></b>	67
			232	388	14	0	0
	5	•	381	738	0	0	0
29-h deprivation	3		67	573	0	0	<b>.</b>
	4		1,015	1,301	153	19	0
-	S.		1,697	1,592	12	2	0

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• :



888-426-4435. Where knowledge is your lifeline.

March 30, 2004

Bill Lafield Vice President of Communications CSPA 900 17<sup>th</sup> Street NW Suite 300 Washington, DC 20006

Dear Bill,

The ASPCA Animal Poison Control Center supports the general concept of adding taste aversive deterrent substances to potentially toxic commercial products in order to protect animals and children by significantly decreasing the amount consumed and thereby averting poisoning. However, we are not aware of any well-controlled published scientific research demonstrating that dogs can be consistently protected from poisoning through the addition of taste aversive agents including denatonium benzoate. Furthermore, we are concerned that pet owners will have a false sense of security if products containing taste aversive substances were marketed as "safer" for use in households with pets.

Without scientific data demonstrating that commercial products containing taste aversive deterrent agents consistently protect dogs from consuming toxic amounts of commercial products, we do not feel that legislation requiring the addition of taste deterrents to certain commercial products to protect animals is appropriate at this time.

Sincerely F J. Steven R. Hansen, DVM

Diplomate, ABT, ABVT Senior Vice-President ASPCA Animal Poison Control Center

en d**og** Location Specification

Admin: 217-337-5030

1717 South Philo Rd., Suite 36 Urbana, Illinois 61802

#### Clean Water Action • Earthjustice

#### Sierra Club • U.S. Public Interest Research Group

#### Please Oppose H.R. 2567

May 23, 2006

Dear Environment and Hazardous Materials Subcommittee Member:

Our organizations write in opposition to H.R. 2567, the Antifreeze Bittering Act of 2005, which would waive liability for the industries involved in producing and selling antifreeze and coolant that contains denatonium benzoate, or "DB." We would oppose liability waivers for other bittering agents as well.

As you know, many antifreeze products contain ethylene glycol, which is a poisonous substance. Adding DB, which has an extremely bitter flavor, is intended to reduce antifreeze poisonings. We support reducing poisonings, but our organizations oppose relieving an industry of its responsibility for personal injuries, property damage, polluted groundwater and economic losses caused by their product.

In light of the nation's problems with MTBE, it is particularly ill-advised for Congress to provide a liability waiver for a chemical such as DB that may not readily biodegrade, for which there is little human health data, and which could end up in drinking water supplies. Liability waivers for products that have the potential to cause health or environmental harm eliminate manufacturers' incentives to create safer products or warn the public about product hazards, shift cleanup costs away from responsible parties, and leave injured people without any recourse. The liability waiver in H.R. 2567 is so broad that it immunizes manufacturers and users of DB from having to take any responsibility for harm caused by their product, even in cases of death.

There is insufficient toxicity data to show that DB is safe for people or the environment. A June 30, 2004 Congressional Research Service memorandum found that "data on toxicity and exposure are too sparse to provide a sound scientific basis for assessing the environmental risks of denatonium benzoate..." However, according to the Food and Drug Administration, some applications of this chemical are not "generally recognized as safe." Some studies have shown that DB persists in the environment and can spread throughout water.

Nor is it clear that adding DB to antifreezes composed of ethylene glycol reduces poisonings. A study of Oregon law that mandated DB in automotive products found it was not necessary and failed to produce any measurable reduction in childhood poisonings. The study concluded that, "There is no compelling reason to consider similar legislation in other jurisdictions." In March, 2004 an official of the Animal Poison Control Center wrote: "Without scientific data demonstrating that commercial products containing taste aversive deterrent agents consistently protect dogs from consuming toxic amounts of commercial products, we do not feel that legislation requiring the addition of taste deterrents to certain commercial products...is appropriate at this time."

Rather than granting a product liability exemption to corporations that produce and use DB, Congress should promote policies to produce environmentally sound products. There are companies that currently produce antifreze using propylene glycol, a much safer chemical than ethylene glycol. The American Journal of Emergency Medicine lists numerous fatalities related to ingestion of ethylene glycol, but none related to propylene glycol. The federal Agency for Toxic Substance and Disease Registry states that "large amounts of ethylene glycol can damage the kidneys, heart, and nervous system. [However,]

[p]ropylene glycol is generally regarded as safe for use in food." This statement provides a striking contrast between the potential safety of these two substances.

We do not oppose aversive agents in antifreeze. The State of California estimates that one manufacture who supplies five percent of antifreeze products in the U.S. already uses DB. If one manufacturer is producing a product with this chemical in the absence of any federal liability wavier, why is a liability waiver even necessary?

In addition, the federal government should not preempt States' ability to provide more protection than a federal floor, nor their ability to hold companies that utilize DB accountable for pollution or harm. Language in H.R. 2567 would do just that, and would even prevent States from adopting standards for bittering agents that could be more effective and safer than DB.

For all of the above reasons – for the health and safety of people and the environment – we urge you to oppose this legislation. Thank you for considering our views.

Sincerely,

Paul Schwartz National Policy Coordinator Clean Water Action

Debbie Sease Legislative Director Sierra Club Joan Mulhern Senior Counsel Earthjustice

Anna Aurilio Legislative Director U.S. Public Interest Research Group



July 16, 2004

Macfarlan Smith Limited 10 Wheatfield Road, Edinburgh EH11 2QA Scotland United Kingdom

Re: Scientific Risk Information Concerning Certain Bitterants

Dear Ms. Jackson:

As you know, a number of U.S. states have adopted legal requirements that certain automotive products -- particularly ethylene glycol-based antifreeze and engine coolants -- contain prescribed levels of aversive agents/bitterants. The sponsors of these laws typically say that the requirements are necessary in order to prevent the accidental poisoning of children and animals. The Consumer Specialty Products Association (CSPA) includes in its membership companies that produce automotive products which are subject to these requirements.

CSPA believes that there is no demonstrated scientific basis for these state and local requirements. Further, existing studies and records indicate that, with respect to those jurisdictions that have enacted such laws, there is no credible scientific evidence showing that the inclusion of bitterants in such automotive products has resulted in a reduction in incidents of accidental poisoning.

The chemical and toxicological profiles of ethylene-based antifreeze are well documented. Company product stewardship programs communicate information about the health and environmental hazards associated with such products, and there is general consensus among product-safety experts that child-resistant packaging and labeling are the most effective means for limiting accidental exposures of these products to small children and animals.

In addition, we believe that any additional requirements for the inclusion of bitterants in antifreeze and other [automotive products/engine coolants] should be deferred at least until such time as full toxicological, exposure and risk evaluations are publicly available for the bitterants themselves -- both as discrete chemicals, and as incorporated into automotive products. Just as our members have developed scientific profiles of their automotive products, it is important both that comprehensive scientific assessments of the bitterants be performed, and that the complete results of those assessments be made available to the producers of the automotive products, to government officials, and to the general public. This has not happened to date.

Serving Makers of Formulated Products for Home and Commercial Use Since 1914 900 17<sup>th</sup> Street, NW, Suite 300 • Washington, DC 20006 • T: 202.872.8110 • F: 202.872.8114 • www.cspa.org Page 2 of 2 The Consumer Specialty Products Association

Enclosed is a summary of key "Basic Test Battery" (i.e. "baseline") scientific data and assessments that CSPA requests you provide to us concerning the bitterants that you produce and sell (e.g., denatonium benzoate -- aka "DB" and "Bitrex"). Concerning each bitterant that you sell for incorporation into automotive products, please provide to CSPA scientific data and any accompanying evaluations of those data, for each specific item on the enclosed baseline summary. We would appreciate receiving this information by [approx. 60 calendar days from date of this letter]. Also, if you do not have data for a particular item on the enclosed summary, please say so and explain why such data are not available.

We would be glad to discuss our request -- including particular items on the attached summary -- with you. For that purpose, and any other related matter, please contact Bill Lafield at 202-833-7311

Thank you, and we look forward to receiving in the near future the scientific data and assessments for your bitterant product(s).

Sincerely,

Bill Infield

Bill Lafield Vice-President of State Affairs

enclosure

#### **Basic Test Battery**

Based on the example of the HPV/SIDS program under EPA and OECD, a basic battery of testing to provide a reasonably complete basic understanding of potential human health and environmental hazards of a chemical that is likely to be released into the environment would include the following:

A. Substance Information

- Chemical Identity
- CAS Number
- Name (CAS or OECD name)
- Structural Formula
- Composition of the chemical being assessed, including degree of purity, known impurities or additives, and difference of impurities among products.

#### **B.** Physical-Chemical Properties

- Melting point
- Boiling point
- Relative density
- Vapor pressure
- Partition coefficient (n-octanol/water)
- Water solubility

#### C. Environmental Fate

- Photodegradation
- Stability in water
- Transport and distribution between environmental compartments including distribution pathways [including Henry's Law constant, aerosolization, volatilization, soil adsorption and desorption, either based on experimental data or if not available or appropriate, calculated using structure-activity relationships (SARs)]
- Aerobic biodegradability
- Nature and identity of breakdown and biodegradation products [may include toxicity testing of major breakdown products, particularly if such products are not also major mammalian metabolites].

#### **D.** Environmental Toxicology

- Acute toxicity to fish
- Acute toxicity to Daphnia
- · Toxicity to algae
- Chronic toxicity. Necessity determined based on physical chemical properties of the chemical. Any new data required should be collected using the most sensitive species (fish, daphnia or algae) within limitations of the chemical properties.
- The need for information on toxicity to terrestrial organisms would be based on the outcome of the initial test battery, particularly mammalian and aquatic toxicity testing and environmental fate data

1/12/06

## E. Mammalian Toxicology

- Acute Oral Toxicity
- Repeated Dose Toxicity. •
- Genetic Toxicity. Two end points required, generally point mutation and chromosomal ٠ aberrations.
- Reproductive Toxicity. Requires data to assess fertility and developmental toxicity.
- Experience with Human Exposure (if available).
- Irritation and sensitization (if available). •
  - Skin irritation
     Eye irritation

The outcome of such a battery of testing would permit a reasonable, scientific assessment of potential human health and environmental risks, or identification of the need (if any) for additional testing.

1/12/06

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Mr Bill Lafleid Vice President of State Affairs Consumer Speciality Products Association 800 17<sup>th</sup> Street NW Washington, DC 20006

Dear Mr Lafield

01 September 2004

Thank you for your letter of July 16, 2004 requesting the data base for Bitrex®. While we are the original discoverers and the company that developed Bitrex® (denatonium benzoate), we will not be sending the individual studies to CSPA that you requested. We do so to protect both our intellectual property as well as that of our customers, including members of the CSPA with whom we do business.

As you are probably aware, the use of denatonium benzoate in antifreeze products is primarily foreign generic imported products. Accordingly we are not actively competing in this generic market or participating in the adoption of legal requirements at the local, state or federal level in the US or elsewhere.

As our Bitrex@ products are of the highest purity and quality we are only active in markets where our trademarks and scientific studies are protected, and technical support provided. Our investments in this regard are recovered in a reasonable time from sales. We do not see this as possible in your request, and do not wish to make our work available to foreign competitors where the specific studies can be used in other markets within the US and elsewhere.

Summaries of our data are readily available via our MSDS sheets and through various references. We trust you understand our position on this matter.

Thank you for your interest in Bitrex®.

Yours sincerely

D'heland Holenon

Dr Melanie H Jackson Bitrex® Development Manager

buik satives, fine chemicais,

Registered address: 2-4 Cockspur Server, London SW1Y SBQ

September 24, 2004

Ms. Linda-Jo Schierow Congressional Research Service Library of Congress LM Room 423 101 Independence Ave, SE Washington, DC 20540

Dear Ms. Schierow:

It was a pleasure talking with you last week and I appreciate your accommodation of CSPA's request for time to gather the appropriate responses to these questions. Below is a brief summary of the Consumer Specialty Products Association's (CSPA's) relevant data on your questions. However, we strongly urge you to examine the included binder for extensive information on the relationship between antifreeze and the bittering agent denatonium benzoate.

CSPA is a national nonprofit trade association representing approximately 240 companies engaged in the formulation, manufacture, distribution and sale of consumer and institutional products. Our members provide a wide range of products including automotive products such as antifreeze.

1. What is the total volume of antifreeze sold in the U.S. annually?

**Response:** Our most recent voluntary survey data indicates that 182,292,138 gallons of antifreeze were sold in 2000. This data has been fairly consistent over the last ten years; from 1990 to 2000 the average amount of antifreeze sold was 181,003,585 gallons. These numbers represent only civilian sales, government sales are not included.

2. What is the total volume of U.S. consumer antifreeze products sold?

**Response:** According to our most recent voluntary survey data (2000) there are two sizes of consumer products sold; quart containers and gallon containers. In 2000, there were 158,130 gallons of quart containers sold and 86,841,391 gallons of gallon containers sold; combined this equals 86,999,521 gallons of consumer antifreeze product sold in one year (2000).

3. What volume of antifreeze is released annually into the environment?

**Response:** Most antifreeze is properly disposed of through municipal solid waste management programs and recycling efforts. The U.S. Environmental Protection Agency estimates that over 12 percent of all antifreeze produced in the United States is recycled each year.

Ms. Linda-Jo Schierow September 24, 2004 Page 2 of 2

In addition, Antifreeze manufacturers are actively encouraging the recycling of used antifreeze thorough product labels and websites; and when recycling is not available, they encourage the proper disposal of antifreeze according to municipal programs and requirements.

Another important fact is that Ethylene Glycol based antifreeze readily breaks down into carbon dioxide and water in the environment in a matter of days, depending upon environmental conditions (*see* Binder Tab 1). This occurs through the natural biodegradation process. However, antifreeze manufacturers continue to have concerns about the lack of biodegradation of the bittering agent (denatonium benzoate). Please refer to the included binder, which documents a wealth of scientific data that forms the basis of these concerns.

4. What volume of bittering agent is required to render antifreeze unpalatable?

**Response:** California and Oregon laws require manufacturers to include a bittering agent in antifreeze sold in these two states. California law specifically requires manufactures to, "include denatonium benzoate at a minimum of 30 parts per million" (*See* Cal. Bus. & Prof. Code §17582). To reach and / or exceed this level of bitterness our manufacturers formulate entire batches of antifreeze with a bittering agent. Therefore, the volume needed to reach this level it is small per gallon. To reach this level of bitterness in a gallon will take 0.018 wt percent of a 20 percent bittering agent (denatonium benzoate) mixture. So to bitter one gallon (which is approximately 9.4 lbs/gallon) to the 30 part per million level, it would take approximately 0.00169 lbs/gallon of a 20 percent bittering agent solution.

It is also important to note that a medical team studying the effectiveness of Oregon's bittering agent law in reducing accidental human exposures in Oregon has concluded, "(The mandatory addition of DB (the bittering agent denatonium benzoate) to automotive products has produced no measurable reduction in unintentional pediatric toxic alcohol exposures in Oregon. There is no compelling reason to consider similar legislation in other jurisdictions." This study by Michael E. Mullins, MD, of Washington University School of Medicine, and B. Zane Horowitz, MD, of the Oregon Poison Control Center, was published in *Veterinary and Human Toxicology* in June 2004. (*See* Binder Tab 19)

Again, CSPA appreciates the opportunity to provide this information. We hope these responses are helpful and would strongly encourage you to examine the extensive scientific research that we have gathered on the issue of bittering agents in antifreeze. Please contact me if you need additional information.

Sincerely,

Andy Hackman Manager, State Affairs Programs

Cc: Phil Klein, Senior Vice President, Legislative and Public Affairs

## SUMMARY OF SCIENTIFIC STUDIES ON THE ENVIRONMENTAL FATE OF DENATONIUM BENZOATE

- Studies by Roy F. Westin, Inc. -- general conclusion: unlike ethylene glycol, denatonium benzoate does *not* fully degrade in the environment.
  - a) Study No. 92-042 (August 8, 1992) considered the effects of denatonium benzoate on the organisms used in publicly owned treatment works (POTWs). The test was conducted to establish what levels would inhibit the organisms, providing data for the design of the next study.
    - i) <u>Note</u>: chloride is salt. Denatonium chloride is a simple version of denatonium benzoate, the chloride replaces benzoate to facilitate the research. The denatonium is the bitter chemical, thus the substitution of chloride for benzoate had no material effect on either the study or its conclusion.
    - ii) The study found that denatonium chloride did *not* biodegradable and would pass through POTWs.
  - b) Study No. 92-051 (August 27, 1992) assessed whether denatonium benzoate or stays in the sludge produced by POTWs. Specifically, the study addressed the issue of what happens when antifreeze is disposed of down-the-drain. It is necessary that all the organics treated by POTWs are biodegradable -- otherwise organic material will remain in the treated wastewater. The study conducted tests to assess the "removablitity" of denatonium benzoate during treatment.
    - i) The study concludes that denatonium benzoate does not biodegrade.
    - ii) The table at p. 7 shows that denatonium benzoate does not biodegrade (*i.e.*, it was not removed during the treatment process) and that it remains in the water and was not removed with the sludge.
  - c) Study No. 92-052 (August 31, 1992) -- this study also simulated a sewage treatment facility to determine what happens to denatonium benzoate when you put it down-the-drain.
    - i) The study concludes that if you put denatonium benzoate down-the-drain, it goes right into the water and does *not* biodegrade.
    - ii) Specifically, the graph at p. 20 compares the biodegradability of glucose and denatonium chloride. In summary, the study concluded that over a 30-day period, the denatonium benzoate stays within the margin of error of not be broken-down into CO<sub>2</sub>-- *i.e.*, denatonium benzoate does not biodegrade and remains in the wastewater.

- The upward sloping line shows that glucose is "eaten" by the organisms during the treatment process (as measured by the production of carbon dioxide).
- (2) By contrast, the two flat lines show that the denatonium benzoate produces no CO<sub>2</sub> -- in other words, the denatonium benzoate is not "eaten" or "digested" by the organisms.
- d) Study No. 93-087 -- in rural areas, some people may dispose of used EG by pouring it on the ground. Thus, this study assesses whether or not denatonium benzoate would stick to the soil or travel with the groundwater.
  - The study concludes that there is minimal environmental impact when EG is poured on the ground since it biodegrades -- in other words, EG does <u>not</u> go into the groundwater.
  - ii) However, the study concludes that denatonium benzoate does not "stick" in the soil. Rather, it stays in and travels with the groundwater. Therefore, it is reasonable to expect contamination problems as the denatonium benzoate accumulates in the groundwater -- the net result is that the groundwater may become bitter (and thus, well water in the area would potentially be unpotable).
- Study by the ENVIRON Corporation (April 6, 1992) evaluated everything related to denatonium benzoate in antifreeze. Specifically, the report addressed the following issues:
  - a) At what level is denatonium benzoate bitter?
  - b) What is the thermal degradability of denatonium benzoate -- in other words, what happens when denatonium benzoate is used in a car's radiator? [Note: the term "degradability" is defined at p. 20].
  - c) Figure 1 (see p. 3) diagrams the chemical compounds that comprise both denatonium and benzoate (note benzoate is an average add-on chemical compound that is used to make the product soluble).
  - d) The study concludes, "...it appears that at automobile engine operating temperatures and at boilover temperatures, there is decomposition of Bitrex.... At 50° C, Bitrex in the same anti-freeze degraded over a period of four months to about half its original concentration " (See p. 4). As a practical matter, 50° C is a rather low temperature for an operating automobile engine (*i.e.*, it's not very hot; the normal engine operating temperatures range from 80° 100° C).
  - e) Figure 2 (see p.6) provides the scientific experts' "best estimate" as to what happens to denatonium benzoate during thermal degradation. [Note: the scientists

do not have a definitive knowledge of what chemical compounds are created when denatonium benzoate breaks-up during the thermal degradation process].

- f) The study concludes, "The fact that ethylene glycol can readily be absorbed through the skin may mean a high potential exposure of Bitrex in anti-freeze than Bitrex."
- g) The study considered the toxicology of denatonium benzoate and concludes that during the thermal degradation process, the bitterness of denatonium benzoate dissipates and that <u>potential carcinogens</u> may be formed.
  - i) Specifically, the study concludes, "Another oxidation product 2,6-dimethylaniline is apparently a mutagenic compound that has been reported to be carcinogenic in animal studies." See p. 10.
  - ii) Thus, requiring manufacturers to include denatonium benzoate in products could potentially trigger the requirement for providing a Prop. 65 warning.
- h) Therefore, it could be argued that the company that is marketing denatonium benzoate put a product in the stream of commerce without conducting reasonable scientific studies to determine the environmental fate or the effectiveness of the product.
- SAE International Technical Paper No. 930587 -- this study is a good source of scientific information.
  - a) The study concludes that denatonium benzoate does not biodegrade in the environment. As a practical matter, the lack of biodegradability is a serious concern when something is as bitter as denatonium benzoate since it could accumulate in water and render it unpotable.
  - b) The study concludes, "The dneatonium ion was not removed by microbial degradation or by adsorption onto the sludge solids in Semi-continuous Activated Sludge (SCAS) test. The lack of CO<sub>2</sub> production corroborated the lack of biodegradation observed in the SCAS test. The intact denatonium ion in the test effluents after treatment in the SCAS and CO<sub>2</sub> production tests was confirmed by HPLC." (See Abstract at p. 1).
- U.S. Consumer Product Safety Commission's (CPSC's) Final Report: Study of Aversive Agents -- an independent scientific study conducted by an agency of the U.S. Government.
  - a) The study concluded, "The limited data suggest that denatonium benzoate does not totally biodegrade. The environmental impact of this is unknown." (See Executive Summary at p. 3).

- b) The study also concluded, "...there is no evidence that denatonium benzoate or any other possible aversive agent is actually effective at limiting ingestion of consumer products." (See Executive Summary at pp. 3-4).
- c) Moreover, the CPSC asserts, "Consumer products containing aversive agents should not be labeled or promoted as being safer than products not containing aversive agents. "
- d) As a result of the overwhelming number of uncertainties about the effect of denatonium benzoate, the CPSC decided not to require the inclusion of denatonium benzoate in products. The report states, "The CPSC recommends that the use of aversives should not be considered for regulation until the effectiveness of these substances to limit ingestions is demonstrated."
- 5) American Association of Poison Control Centers (AAPCC) reported on all reported exposures to ethylene glycol for a two-year period. [Note: this report included all reported exposures throughout the entire country for a two-year period]. Over this two-year period, only 6-8 children were reported to have been exposed to ethylene glycol and none of these exposures were life-threatening.
  - a) The data reported at pp. 1-2 indicate that there was no medical effect of the exposures to ethylene glycol.
  - b) The data reported at p. 3 reflect some minor effect -- in other words, the poison control centers received reports that there had been an exposure to ethylene glycol, but that there was no toxicity.
    - i) <u>Note</u>: the children that were reported to have been exposed to ethylene glycol were, for the most part, very young. The proper use of secured child-resistant closures would have likely prevented such exposures.
    - Note: child-resistant closures already protect unused antifreeze that is properly stored in its original container -- however, the effects of thermal degradation cause Bitrex to break-down and thus, the chemical does *not* have any effect in used antifreeze.
  - c) The data reported, at pg. 4, reflect <u>all</u> the exposures throughout the entire country over a two-year period; these were cases in which medical personnel could measure the exposure to EG in either the blood or urine -- BUT, these exposures were NOT life threatening.
    - i) It is interesting to note that there were two cases in which the exposure appears to be the result of an intentional misuse of the product.
    - ii) In one case, EG was used by a 27year-old male in conjunction with cocaine.
    - iii) In another case, the exposure occurred when a 78 year-old male ingested EG in conjunction with varnish or lacquer.

- d) The data reported at p. 5 reflects only one serious exposure that resulted from accidental misuse -- but there were *no* deaths.
- e) The data reported at p. 6 reports two uncharacterized exposures -- in both cases, children were involved. But, importantly, there was no reported adverse medical effect from either of these exposures.
- 6) Procter and Gamble performed marketplace tests, by including denatonium benzoate in two of its detergents. The purpose was to determine if adding denatonium benzoate alters the frequency of accidents, and did denatonium benzoate alter the ingestion volume. (P&G monitored ingestion through their 800-line calls)
  - a) During trials no change in the frequency in the rate of calls
  - b) Concluded that denatonium benzoate does not reduce the incidence or severity of ingestions.
- 7) In 1993, the Oregon Department of Environmental Quality concluded that there was insufficient data to perform a reliable environmental fate assessment.
- 8) An agenda for an internal ASTM meeting to determine the stability of denatonium benzoate through thermal change similar to car engines. This document shows that as early as 1990, there were significant uncertainties about the thermal degradation of denatonium benzoate in antifreeze.
  - a) It was determined that denatonium benzoate is stable when dry but when heated it is broken down quickly.
  - b) It was determined that because denatonium benzoate breaks down quickly, it will not be effective in used antifreeze.
  - c) Thermal degradation causes denatonium benzoate to break down into other chemicals. These unknown compounds will be going into the environment.
- 9) BASF letter dated January 21, 1993, provides anecdotal background on why Sweden requires denatonium benzoate in antifreeze. Since there is a high tax imposed on alcoholic beverages in Sweden, "winos" were drinking antifreeze in order to get admitted into state hospitals where the remedy was to give injections of ethanol. The winos relied upon these injections to get "high."
- 10) First Brands letter dated August 12, 1991, summarizes Prestone's position on the issue of including aversive agents in consumer products.
- 11) Montell Chemical Senses Center is the top research firm for taste and smell. In a letter dated August 7, 1991, as the preeminent experts in taste perception, Monell concluded that denatonium benzoate would not stop small children from ingesting

small amounts of antifreeze since denatonium benzoate takes approximately 2 seconds to work.

- 12) The Texaco letter August 26, 1991, presents the company's conclusion -- based upon tests in fleet car and animals -- that Bitrex was not an effective deterrent to animal ingestion. Specifically, as a result of thermal breakdown of denatonium benzoate in antifreeze, product that leaked from cars would not be have an aversive effect on dogs. Moreover, it concluded that antifreeze is unpalatable to dogs -- with or without Bitrex
- 13) The First Brands letter dated August 27, 1993, conveys information to the antifreeze manufacturers' attorney (Mr. DiLorenzo) in the Oregon case. The letter provides a summary of the Dow study dated March 30, 1992,
- 14) The document from Dow Chemical Canada presents an analytical summary of Dow's data. The study was issued on March 30, 1992. This study was referenced in the Environ Corporation's study (see #2 above).
- 15) BASF Handout concludes that denatonium benzoate thermal stability is very weak and that denatonium benzoate breaks down in engines.
- 16) Several documents, beginning with a study on dogs conducted by Pharmakon Research International, Inc., entitled "Comparative Experimental Oral Assay in Dogs." This document measured the palatability of denatonium benzoate in dogs. The study reached the following conclusions:
  - a) Aversive agents will not reduce danger posed to animals
  - b) Aversive agents will not "poison-proof" antifreeze
- 17) MSDSs of products containing Denatonium Benzoate
  - a) Rentokil Initial Products: Safety Data Sheet for "Rodine C (with Bitrex)". pg. 4, section 12 (Ecological Information) indicates that the product should not be disposed of near water.
  - b) C-TECHCORPORATION: Material Safety Data Sheet for Denatonium Benzoate. pg. 5, section 15 (Regulatory Information)
    - i. The German Water Hazard Classes
    - ii. Definition and Classification of Substances hazardous to water

- 18) Letter from the American Society for the Prevention of Cruelty to Animals' (ASPCA's) National Poison Control Center, dated March 30, 2004. States that ASPCA does not support legislation that mandates the inclusion of aversive agents in commercial products
- 19) Medical study by Michael E. Mullins, MD, of Washington University School of Medicine, and B. Zane Horowitz, MD, of the Oregon Poison Control Center, published in *Veterinary and Human Toxicology* in June 2004, entitled "Was it Necessary to Add Bitrex (Denatonium Benzoate) to Automotive Products?"
  - a) Concludes that Oregon's aversive agent legislation has had no measurable impact in reducing exposures to antifreeze.
  - b) States that "There is no compelling reason to consider similar legislation in other jurisdictions." (pg. 152).

#### Was it Necessary to Add Bitrex (Denatonium Benzoate) to Automotive Products?\*

#### Michael E Mullins MD

Division of Emergency Medicine, Washington University School of Medicine, St Louis, Missouri

#### B Zane Horowitz MD Oregon Poison Center, Oregon Health Sciences University, Portland, Oregon

ABSTRACT: Oregon was the first state to mandate the addition of a bitter aversive agent to consumer automotive products containing  $\ge 10\%$  ethylene glycol (EG) or  $\ge 4\%$  methanol (MeOH). The 1995 Toxic Household Products statute required the addition of denatonium benzoate at a concentration of 30-50 ppm with the intent to reduce the frequency of serious pediatric exposures to these products. Retrospective review included Oregon Poisson Center (OPC) records of all reported pediatric (< 6 y) exposures to automotive antifrezez (EG) and windshield washer fluid (MeOH) from 1987 through 2003, OPC charts of children treated with ethanol, fomepizole, or hemodialysis for EG or MeOH poisoning from 1987 through 2002, and coroner reports of poisoning deaths for 1994-1997 to identify EG or MeOH deaths not reported to the OPC. OPC recorded 332 EG and 117 MeOH exposures among preschod children from 1987-2003 with no change in annual frequency alter (1955. No child died or suffered ingior effects before or after 1995. Ten children received ethanol infusions until laboratory results were available; 9 had no detectable concentration of the suspected agent, and 1 had a sub-toxic determined in the determined of the other part determined and the results of the other sub-toxic determined adversion determined and the determined activity of the suspected agent, and 1 had a sub-toxic concentration. Two children received fomepizole but had no detectable EG. No child underwent hemodialysis. Coroner reports detected no missed pediatric deaths from toxic alcohols in 1994-1997. The mandatory addition of denatonium benzoate was unnecessary as unintentional ethylene glycol or methanol exposures in pre-school age children did not cause measurable toxicity.

In 1991, the Oregon Legislature passed the Toxic Housein 1991, the Oregon Legislature passed the Toxic House-hold Products statute mandating the addition of a bitter aversive agent to consumer automotive products contain-ing  $\geq$  10% ethylene glycol (EG) or  $\geq$  4% methanol (MeOH). Oregon was the first state in the U.S. to require a bitterant regardless of whether the product had child-resistant pack-aging. The intent of the Toxic Household Products (THP) statute was to reduce the perceived risk of unintentional pediatric poisonings by EG and MeOH. Intensive lobbying and lead action building the toxic the term of the toxic the term of the toxic term of the term of the toxic term of the term of term of the term of the term of the term of the term of term of term of term of term of term of the term of term of term of term of the term of ter and legal action by industry delayed implementation until 30 April 1995. Subsequent clarification of the law required the addition of denatonium benzoate (*Bitrex* â, MacFarlan Smith Ltd, Edinburgh, Scotland; marketed in the US by Henley Chemical Co, Montvale, NJ) at a concentration of 20 60 nome 30-50 ppm.

The purpose of this study was to compare the incidence of exposures to the toxic automotive alcohol products before and after implementation of the law,

#### MATERIALS AND METHODS:

We reviewed the Oregon Poison Center database from January 1, 1987 through December 31, 2003 for the outcomes of pediatric cases involving automotive products containing EG or MeOH. We excluded exposures to other automotive prod-ucts, such as brake fluids and glycol ethers, which were not affected by the THP statute. Experienced registered nurses trained and certified as Specialists in Poison Information clas-stified the outcomes as "no effect", "minor", "moderate", "ma-jor", "death", or "unknown" in accordance with standardized reporting guidelines for the American Association of Poison Control Centers Toxic Exposure Surveillance System (AAPCC TESS) (1). We searched the database to identify treated with ethanol infusion and/or hemodialysis for EG or

\* This information was presented as a poster at the North America Congress of Clinical Toxicology, San Diego, CA, October 1-4, 1999.

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MeOH poisoning for 8 y before and 8 y after THP implementa-tion. We reviewed the individual charts of all cases in which children received antidotal treatment with ethanol or fomepizole. We also reviewed medical examiner reports of poisoning deaths recorded by the state health division for the years 1994 through 1997 to identify poisoning deaths not reported to the Poison Center.

#### RESULTS

Review of the EG exposures reported to the Oregon Poison Center from 1987 through 2003 revealed 332 exposures to au-Center from 1987 through 2003 revealed 332 exposures to au-tomotive products containing EG among children < 6 y of age. Clinical effects were "none" in 231 exposures (70%), "minor" in 28 (8%), "moderate" in 2 (0.6%), "unknown" in 46 (14%), unre-lated in 22 (7 %), and "confirmed non-exposure" in 3 (0.9%). No case resulted in "major" effects or death. The probability that a "major" or fatal EG case would occur in any subsequent year was 0% (95% CI 0 to 0.9%).

Review of MeOH exposures reported to the OPC from 1987 Neview of mechanisms reported to the OPC from 1987 through 2003 revealed 117 exposures to automotive products containing MeOH among children < 6 y of age. Clinical effects were "none" in 84 (72%), "minor" in 13 (11%), "moderate" in 3 (3%), and unknown in 17 (15%). No case resulted in "major" effects or death. The probability that a "major" or fatal MeOH case would occur in any subsequent year was 0% (95% CI 0 to 2.5%).

Excluding the data for 1995, the year that the THP statue Excluding the data for 1995, the year that the THP statue went into effect, comparison of the 8 preceding years (1987-1994) and the 8 following years (1996-2003) showed no change in the number of reported pediatric exposures to automotive EG and MeOH (Fig 1). The means (+/- SD) for EG exposures reported annually were 17.8 (+/-5.2) from 1987 through 1994 and 20.6 (+/-6.7) from 1996 through 2003 (p=0.36, two-tailed, unpaired t-test). The means (+/- SD) for MeOH exposures reported annually were 6.3 (+/-1.7 from

an old rum bottle. No deaths occurred in the pre-school age population

The deterrent effect of denatonium benzoate (DB) is debatable. Two studies indicated that children drank smaller volumes of orange juice and dilute solutions of liquid dishwashing soap when the products contained DB (23, 24). The manufacturer promotes the product as being "the bitterest substance known to man" and has advocated for laws to add it to potentially toxic household products. Proctor and Gamble voluntarily added DB to 2 liquid laundry detergents and found no difference in the fre-quency of consumer calls to the company's toll-free information line regarding exposures to these 2 products compared to simi-lar products without DB (25). While this is probably not a scien-tific measure of DB's deterrent value, Jones and colleagues found a small subset of ethanoi intoxicated drivers in Sweden who con-sumed cheaper technical alcohol despite the addition of DB and a red dye to deter consumption (26).

A recent case report from France describes a 4 y-old 14 kg female who drank antifreeze containing 41% EG and 113 ppm Bitrex (27). She presented with metabolic acidosis, an anion gap of 29 mmol/L, and an osmolar gap of 50 mOsm/L, Although not measured, her calculated EG concentration was 50 mmol/L (310 mg/dL). She received treatment with fomepizole and recovered without hemodialysis, ethanol infusion, or so-dium bicarbonate. Based upon her calculated peak EG con-centration and a volume of distribution of 0.6 L/kg for EG, she may have ingested approximately 20 mL of antifreeze. This occurred despite a concentration of DB well in excess of the concentration reported to be deterrent (23, 24, 28) and 3 times the concentration used in Oregon.

In October 2002, California became the 2nd state to mandate the addition of DB in automotive antifreeze containing EG, but not in MeOH-containing products. This law became effecbit in the off an integration of the products. This fair because and the incidence of pediatric EG ingestions in California will be unaffected by this law.

The first law mandating addition of DB was never neces-sary, as unintentional EG or MeOH exposures in pre-school age children did not cause measurable toxicity. The manda-tory addition of DB to automotive products has produced no measurable reduction in unintentional pediatric toxic alcohol exposures in Oregon. There is no competiting reason to con-dice clearly installing in a that indications sider similar legislation in other jurisdictions.

#### ACKNOWLEDGMENT

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Chair Environment and Hazardous Materials Subcommittee Energy and Commerce Committee 2125 Rayburn House Office Building Washington, DC 20515

The Honorable Hilda Solis

The Honorable Paul Gillmor

May 11, 2006

Ranking Member Environment and Hazardous Materials Subcommittee Energy and Commerce Committee 1725 Longworth House Office Building Washington, DC 20515

Dear Chairman Gillmor and Ranking Member Solis:

On behalf of the members of the American Veterinary Medical Association, I am writing in support of H.R. 2567, the Antifreeze Bittening Act of 2005, which is currently in the Environment and Hazardous Material Subcommittee. We look forward to a hearing on this legislation in your subcommittee this month, and would like this letter to be entered into the record as written testimoay.

Each year, thousands of animals ingest antifreeze and engine coolant. Ethylene glycol, the most common active ingredient in antifreeze and engine coolant, is highly toxic to companion animals and wildlife. Small amounts of ethylene glycol (less than ½ a teaspoon per pound of body weight for a dog) can cause rapid kidney failure and death. Treatment of Ethylene Glycol toxicity requires intensive care and is very costly. In addition, pet owners are emotionally devastated by the severity of this unfortunate poisoning.

H.R. 2567 requires engine coolant and antifreeze to contain a bittering agent so as to render it unpalatable. This is consistent with AVMA's policy on Ethylene Glycol: The AVMA commend manufacturer and distributors of thylene glycol for providing clear warning ideals that emphasize the potential danger of this product to animals. The AVMA for there ensures continuation of this practice as well as the investigation and implementation of means to reduce the palatability of ethylene glycol preparations to animals.

The companion Senate bill (S. 1110) has been marked up by the Committee on Commerce, Science and Transportation and awaits action by the full Senate.

We appreciate your leadership on this legislation, and look forward to supporting its passage in the 109<sup>th</sup> Congress. If you have questions, please feel free to contact me at 202-289-3205 or mlutschaunig@avma.org.

Respectfully,

Mark Inschannig , Mail HBA Dr. Mark Lutschannig Interim Director AVMA Governmental Relations Division

The AVMA is the recognized voice for the profession, representing over 73,000 member veterinarians. The objective of the AVMA is to advance the science and art of veterinary medicine, including its relationship to public health, biological science, and agriculture.



#### DORIS DAY ANIMAL LEAGUE

#### Response to Questions about the Efficacy of Denatonium Benzoate

Critics of the bill to require the addition of denatonium benzoate (DB) to ethylene glycol antifreeze (H.R. 2567) have pointed to comments from the National Animal Poison Control Center (NAPCC) questioning the efficacy of DB. It should be noted that NAPCC Director Dr. Steve Hansen told members of the AVMA that his literature search turned up neither "supporting" NOR "disputing" data with respect to animals, and that "for children, data do exist indicating that DB may be an effective deterrent."

As we show below, studies supporting the efficacy of DB as a deterrent for animals do exist, *including one on which Dr. Hansen is an author*. Moreover, after reviewing the data, the staff of the California Integrated Waste Management Board (which endorsed adding a bittering agent to ethylene glycol antifreeze) concluded that "animals are indeed deterred from continuing to consume liquids and food that contain denatonium benzoate."

Furthermore, the American Association of Poison Control Centers characterizes ethylene glycol as "an ideal candidate for an aversive agent because of its reportedly 'sweet' taste."

#### Efficacy Issues

Some questions have been raised about whether the addition of DB to antifreeze will indeed prevent poisonings. It is true that data on the efficacy of DB are not abundant, and that data exist on both sides of the question. That being said, however, there is evidence of its usefulness in preventing or mitigating ingestion of substances by children and animals.

For example, in its memo supporting West Harlem Environmental Action v. U.S. EPA, the Natural Resources Defense Council<sup>1</sup>, which is opposing H.R. 2567, wrote:

"...EPA claims that it revoked the bittering agent requirement because of efficacy concerns, but EPA's own analysis disproves these concerns. Before requiring the safety measures, EPA reviewed scientific studies on denatonium benzoate, a possible additive and 'the bitterest substance known to man.' EPA 0113I. A field study of a rodenticide containing 10 parts per million of this bittering agent resulted in a '95% reduction in rodent activity.' *Id.* The same level of bittering agent in different household products 'was found to reduce the amount ingested by children.' *Id.* This record evidence supports the conclusion that a bittering agent can effectively control rats and deter children's exposure."

Suite 100 • 227 Massachusetts Ave., N.E., Washington, D.C. 20002 • 202/546-1761 202/546-2193 E-mail: info@ddal.org • www.ddal.org In 1963, the FDA approved the addition of denatonium benzoate to cosmetic and toiletry products as a safety mechanism to deter children from ingesting these products. It is used in hundreds of products to render them unpalatable, including cleaning agents, other household products, cosmetics, and personal care products—everything from detergents and aftershave to fire extinguisher fluid, gasoline, pesticides and herbicides, ink, wax crayons, nail polish remover, bubble bath, hair spray, and eyeshadow. It is even in veterinary sprays and ointments. In 1989, the U.S. Department of Agriculture approved it for food plant use.

Also, according to the Center for the Science and Engineering of Materials<sup>ii</sup>, DB "is recognized as the bitterest substance known. When it is added in only minute quantities to potentially harmful household, garden or automotive products, this harmless additive renders these products unpalatable and becomes a powerful deterrent against poisoning especially in young children."

Likewise, the CIWMB staff study also found "that the addition of denatonium benzoate may not prevent exposures, but it would significantly reduce the amount ingested, hence the severity of exposures. Numerous studies have shown that it does repel animals, though until it is used extensively in antifreeze, the magnitude of its effectiveness for animals in ethylene glycol based antifreeze will be difficult to verify." A 2001 analysis of data by the staff of the California Integrated Waste Management Board (CIWMB) suggests that it would be ill-advised to make judgments about the efficacy of denatonium benzoate on the basis of experience over a relatively short time period by noting that "[c]omparatively, it took 17 years to conclusively prove that child-resistant caps were effective in reducing child exposures in general."

One such study is "Denatonium benzoate as a deterrent to ingestion of toxic substances: toxicity and efficacy"<sup>iii</sup>, in which the authors, **including the current director of the ASPCA's** Animal Poison Control Center, conclude the following:

"Since there is evidence that some taste aversion agents reduce the quantities of liquid substances ingested by dogs, and there is evidence that denatonium benzoate reduces ingestion quantities by children, denatonium benzoate may reduce the seriousness of accidental exposures to harmful fatal substances in dogs. This deterrent potential in animals needs to be investigated further. *Denatonium benzoate should be added to toxic substances available in and around homes which, when ingested, represent serious hazards to animals and children."* (Emphasis added.)

<sup>ii</sup> "The National Science Foundation sponsors a network of Materials Research Science and Engineering Centers (MRSECs) at U.S. universities. The Center for the Science & Engineering of Materials (CSEM) at Caltech is one of them. The goal of the program is to stimulate interdisciplinary research and education in materials." (CSEM Fact Sheet)

iii Hansen SR, Janssen C, Beasley VR. Vet. Hum. Toxicol. 1993 Jun; 35(3):234-6.

MR. GILLMOR. The gentlelady from New Mexico.

MRS. WILSON. Thank you, Mr. Chairman, and Mr. Willis, thank you for being here. What is the proper way to dispose of antifreeze? When you take your car in to get the coolant changed when it gets to be summertime, what are they supposed to do with it? Do you know?

MR. WILLIS. I am afraid I don't, Congresswoman.

MRS. WILSON. So is this stuff that you are not supposed to put down the drain and dispose of in some other way or is this just a benign chemical that you can put down the sink?

<sup>&</sup>lt;sup>i</sup> West Harlem Environmental Action v. US EPA, Memorandum in Support of Plaintiffs' Motion for Summary Judgment, filed by the Natural Resources Defense Council in US District Court for the Southern District of NY, March 29, 2005; pp15-16

MR. WILLIS. I am afraid I don't actually have the answer to your question, Congresswoman.

MRS. WILSON. You said in your testimony that plain antifreeze has low toxicity and is easily biodegradable. Does that imply that it--that was kind of a surprising statement to me, and I am always taught that you don't put that stuff down the drain.

MR. WILLIS. Congresswoman, I don't think I said it is biodegradable. I think I said it is relatively not biodegradable. And based on my personal understanding, I think it probably does need to be disposed of properly. I am simply ignorant of which law it is that it needs to be disposed of properly under.

MRS. WILSON. But to your knowledge, this bittering agent, DB, which is included in shampoo, laundry detergent, fabric softener, animal repellants, pesticides, bath cleaners, stain removers for clothing, so it is going down our drains in all of those products when we rinse the stuff out of the shower after we have cleaned it, but you are not aware of any contamination problems or environmental problems where a site has been located where the groundwater has been contaminated by DB?

MR. WILLIS. That is correct, Congresswoman. We are not aware of any cases of environmental contamination by DB.

MRS. WILSON. And how long has this substance been routinely used in consumer products?

MR. WILLIS. I think for several decades.

MRS. WILSON. So this is not a case of this being a new thing and we have got some terrible problem to look forward to, this has been on the market and used since I was, probably since I was born, 1963, I think is the date that I recall, so we are talking about several decades of experience with this going down our water systems, right?

MR. WILLIS. Well, yes, with environmental exposure to this chemical, indeed. For example, through its use as a deer repellant or in consumer products.

MRS. WILSON. Or down my drain if I use something to wash the shower or wash clothes or--

MR. WILLIS. Yes, Congresswoman.

MRS. WILSON. Okay. Thank you, Mr. Chairman.

MR. GILLMOR. Thank you. Further questions? The gentleman from Washington. I beg your pardon. I am told Mrs. Capps was first.

MS. CAPPS. Thank you. Thank you for your testimony, Mr. Willis. On the next panel today, we are going to hear testimony from the American Waterworks Association representing 4,800 utilities nationwide to the effect that history is replete with examples of the unintended consequences of measures adopted to obtain laudable goals. MTBE is an example, when added to motor fuels, an example that has left many local governments and drinking water utilities with contaminated water and huge treatment and cleanup costs.

Now, your testimony describes the knowledge of EPA about denatonium benzoate as, and these are quotes, these phrases: "limited information." Another quote, "Not conducted a full risk assessment," and the third one, "No extensive database of toxicity or environmental fate information on DB." And finally, "Not enough information for the agency to conduct a thorough human health or environmental assessment on this chemical."

I ask you if there may be unintended consequences to this bill and whether it is your concern that there may be and if it should be of concern to us, in your position with the Environmental Protection Agency?

MR. WILLIS. Yes, thank you, Congresswoman. DB is, as was noted earlier, is not similar to MTBE.

MS. CAPPS. I know that. I was using it as just an example of something with very good intentions leading to very severe, unintended consequences.

MR. WILLIS. Indeed, Congresswoman, some of the differences between this chemical and MTBE, however, point up some of the differences of a chemical of this nature and chemicals that tend to cause widespread environmental contamination. One of the issues is the concentration a chemical is used at, and this would be used in low concentrations.

MS. CAPPS. I don't want to make a comparison between DB and MTBE. I was only using that as an example. What I am getting at is the level of studies that have been conducted, the numbers of them, the range of them, the variety of them, and this is your agency. Do you consider that there may be, based on your knowledge that you have already in the agency, that there may be unintended consequences that perhaps could be ferreted out ahead of time so that we don't fall into the path that we have on other occasions?

MR. WILLIS. We do not have a concern about a significant health or environmental risk from DB based on our present analysis.

MS. CAPPS. You have enough information that leads you to say there is no reason for concern? Let me phrase it a different way, because I really want to get you to say something that will be useful to us, because this is a tough decision that we have to make. I was on the bill the last time, but now I have questions because I am concerned about the statements that I just gave you that might indicate that there may not be sufficient studies. Let me say it this way. Do you believe that it is in our interest, here on this committee, that there be a full scientific assessment of this chemical conducted before we take a very unusual step, different from the other products in which it is used, of mandating that DB be added to an automotive product?

MR. WILLIS. Congresswoman, I think it is a bit of a challenge for me in my position to, if you will, tell you what I think you should do. I think that would--

MS. CAPPS. You think it would be useful to have a more extensive scientific assessment?

MR. WILLIS. There are some data gaps.

MS. CAPPS. There are some data gaps. Would it be useful to have those gaps filled?

MR. WILLIS. It would depend on a number--

MS. CAPPS. You can't say yes or no?

MR. WILLIS. I cannot say yes or no because it depends on a number of exposure situations where we also don't have the data.

MS. CAPPS. Well, could this be tested out? Exposure situations. Could there be a variety of situations at least examined?

MR. WILLIS. Congresswoman, I feel myself getting in trouble here.

MS. CAPPS. Oh. Let me ask you one more yes or no question. I have about 10 seconds. This is a statement made by the Consumer Specialty Products Association on July 16<sup>th</sup> of 2004 in a letter that they wrote. This is their quote. I want to ask if you agree with them or not. They say and I quote, "We believe that any additional requirements for the inclusion of bitterants in antifreeze and other automotive products or engine coolants should be deferred at least until such time as a full toxicological exposure and risk evaluation be publicly available for the bitterants, themselves, both as discreet chemicals and as incorporated into automotive products." Do you agree?

MR. WILLIS. Congresswoman, we would, for a chemical of this type, with the expected production volume and exposure considerations, we would not be going after more data to conduct a fuller risk assessment.

MS. CAPPS. I yield back.

MR. GILLMOR. Further questions? Mr. Bass.

MR. BASS. Thank you, Mr. Chairman. I will just ask one question. Mr. Willis, you stated that--by the way, this is a follow under the distinguished Ranking Member's comment about the absorptive nature of DB in soil and it says here that you state that the chemical properties of DB would make it unlikely for it to migrate to groundwater because of its propensity to absorb soil unless it is sandy soil. Can you give us a practical explanation of exactly what this means? Does this mean that you think it is a problem if it gets into groundwater or not? If DB is not filtered out by drinking water systems since it does not biodegrade, is it a threat to health or the environment?

MR. WILLIS. Based on our modeling, we think if this reaches the soil, it is unlikely to move through the soil into groundwater at any appreciable rate.

MR. BASS. All right. Well, that is it, Mr. Chairman. Thank you.

MR. GILLMOR. Thank you. Further questions? Mr. Inslee.

MR. INSLEE. Thank you.

Do you think, can the Federal government guarantee that DB will not be harmful to human health in any manifestation?

MR. WILLIS. No, Congressman, we cannot make that guarantee.

MR. INSLEE. And why can't you make that guarantee?

MR. WILLIS. Because we don't have the test data for all possible endpoints, nor do we have the fate and exposure data that would allow us to do that sort of assessment.

MR. INSLEE. So the bill essentially works on the assumption that a guess that the Federal government can guarantee the safety of this product because as a total exemption from liability of the manufacturer of the antifreeze compound, assuming, I guess, that means that we are supposed to be guaranteeing to the public that it is safe so that when we tell a manufacturer to put it in there, that no one has a claim if they are killed or get cancer or have some other health problem. To me that doesn't make any sense. If the Federal government can't guarantee it is safe, we shouldn't be denying citizens a claim against a manufacturer of the product once we tell them to put it in there. Am I right on that?

MR. WILLIS. Congressman, you are drawing me into a position on liability and I think I have noted that the agency doesn't have a position on this bill, including on the liability.

MR. INSLEE. Well, I have a position that if the Federal government can't guarantee the safety of a product, we shouldn't be denying citizens the right for a claim when Congress insists it be in there and that is why I think this blanket liability, and I have read it, it is a blanket liability for the manufacturer of the product as long as the product is put in there according to the Congressional specification. Now, it isn't for the manufacturer of the DB, but that will be the bankrupt corporation that has \$1.20 in their till when people start getting sick, if that were to happen. So I think we have real problems with this liability perspective.

Is there anything that you can give us on a lay basis to characterize that the potential toxicity, biodegradable--I don't know what the word isits characteristic of being biodegradable or not, is there anything else you can put this in kind of a spectrum? Is it benign as mother's milk? Is it as potentially dangerous as DDT? Is it unknown as other products? Is there any kind of spectrum you can give us as something we could-- MR. WILLIS. Well, Congressman, there are a number of chemicals that sort of fall in this low to moderate range. One that members may be familiar with is something called sodium benzoate. Sodium benzoate is commonly found as a food additive. It shows up in soda pop. It may have been in the drinkable green liquid and is in the same general toxicity range as DB.

MR. INSLEE. And can you think of anything else that has a similar characteristic of being biodegradable or not biodegradable?

MR. WILLIS. I would have to get back you on that, Congressman. I can't think of a good example offhand.

MR. INSLEE. I read in your testimony, you made some reference to, again, based on the models of the agency's screening analyses, the compound is predicted to be moderately toxic to aquatic organisms and plants, with fish, aquatic invertebrates, and algae being least to most sensitive, respectively, so that would mean algae would be the most sensitive. Is there any way to characterize that? Aquatic invertebrates second most sensitive?

MR. WILLIS. It is in high concentrations, Congressman, it would likely kill some, but possibly not all algae in a water system. Similarly, it may kill a number of the invertebrates that live in the water column and that fish feed on, although it is less toxic to those aquatic invertebrates than to algae.

MR. INSLEE. So we have a situation where ingestion to pets, we know, can cause death and we know that there is some risk of death to other animals or--it may not be pets, but they are in the animal kingdom, is that the situation?

MR. WILLIS. Congressman, I may have misunderstood your original question. I thought we were talking about DB, but the deaths to pets, I think, are--

MR. INSLEE. Yes, let me rephrase my question. With the death to pets that we are all concerned about here, besides our children, or death to pets that happen when they eat the antifreeze, itself, but in order to prevent that, if we mandate a product that can end up mortal to other animals in the animal kingdom, it is kind of an irony, I guess, that I am troubled by a little bit because they may not be our pets but they are God's creatures and we do have concerns about salmon who live on these little aquatic invertebrates in the Puget Sound and it is just something we ought to think about. Thank you.

MR. GILLMOR. Further questions of the witness? Ms. Schakowsky.

MS. SCHAKOWSKY. Thank you. Mr. Willis, you are Division Director, Chemical Control Division, Office of Pollution Prevention and Toxic Substances. I was a little concerned that you were unable to answer what I think would be a pretty common question, how do you dispose of antifreeze in a safe way. We are talking about, I mean, if part of it is Office of Pollution Prevention, I would think that common substances, particularly those that people use so often and might have, likely have questions about, is that not your field?

MR. WILLIS. That is correct, Congresswoman. Disposal of antifreeze is not one of our office's activities.

MS. SCHAKOWSKY. So who is concerned about pollution prevention, that is how one would dispose of chemical hazard, et cetera? Does anybody oversee that?

MR. WILLIS. Congresswoman, I believe the Office of Solid Waste would oversee that.

MS. SCHAKOWSKY. And antifreeze would fit into solid waste?

MR. WILLIS. Indeed. It would, Congresswoman.

MS. SCHAKOWSKY. Okay.

MR. WILLIS. I would have to get back to you with an answer because it is outside of the realm of our office's work. However, I can tell you what offices in EPA are engaged in that and what they are doing.

MS. SCHAKOWSKY. Okay. Let me understand your response to Ms. Capps' question. We are now in the process, potentially, of mandating the inclusion of a widely used, of a substance in a widely used product and my understanding of what you said, that you would not do any further risk assessments than have already been done on DB, that we could proceed ahead, mandate it, it become law without any more inquiry into DB?

MR. WILLIS. Yes, Congresswoman. If a chemical like DB came into our program with the data that we had readily available to us during the screening level analysis, we would not have taken an action to control the risk of this chemical.

MS. SCHAKOWSKY. The difference between this and many other things is the Federal government is taking, I think, a fairly unusual step, I don't know, to actually mandate the use of a particular product, which is somewhat different than, it seems to me, than examining the toxicity or the environmental impact of just any old product; we are actually going to be mandating that. And to follow up on Mr. Inslee's remarks, the toxicity to fish, aquatic invertebrates, algae, and aquatic plants is predicted, there are environmental impacts that could affect the salmon or others. At what level does that become a concern?

MR. WILLIS. Congresswoman, at the levels that this chemical is estimated to be used at in products, we would not be concerned about these toxicities because those levels would not be expected in, for example, the aquatic ecosystems that we are talking about here.

MS. SCHAKOWSKY. Low to moderate concern for toxicity to humans and mammalian wildlife. Well, moderate concern. Also, I just wanted to point out when our Ranking Member Solis, asked you about a number of other studies and there are all kinds of, there is a whole book of them here and you were unfamiliar with them. Now knowing that there have been studies, and I understand there are some conflicting findings, do you feel obligated to assess those, to add that to your decision making process or your evaluations?

MR. WILLIS. Indeed, Congresswoman. We would very much like to review those studies and add that to our evaluation.

MS. SCHAKOWSKY. So in fact, under certain circumstances, you would increase your risk assessment, that is to look further, perhaps change your view?

MR. WILLIS. Oh, indeed, Madam. Any time data becomes available to us, we are always happy to reevaluate a chemical.

MS. SCHAKOWSKY. Thank you.

MR. GILLMOR. Thank you very much, Mr. Willis. We appreciate you coming. We will call Panel 3 forward. Very well. If the panel is prepared, we will start with Mr. Jeffrey Bye of Honeywell, who is testifying on behalf of the Consumer Specialty Products Association. Mr. Bye.

**STATEMENTS** OF **JEFFREY** BYE, VICE PRESIDENT, PRESTONE, HONEYWELL INTERNATIONAL, INC. ON CONSUMER SPECIALTY PRODUCTS BEHALF OF ASSOCIATION; PATRICE L. SIMMS, SENIOR PROJECT RESOURCES ATTORNEY, NATURAL DEFENSE **COUNCIL:** SARAH AMUNDSON. DEPUTY AND **LEGISLATIVE** DIRECTOR, DORIS DAY ANIMAL LEAGUE; **MELINDA** EYRICH, DVM, **CO-OWNER**, **URGENT CARE VETERINARIAN HOSPITAL; AND TOM** BONACQUISTI, DIRECTOR OF WATER QUALITY AND **PRODUCTION, FAIRFAX COUNTY WATER AUTHORITY** ON OF AMERICAN BEHALF WATER WORKS ASSOCIATION

MR. BYE. Thank you, Mr. Chairman and Ranking Member Solis. My name is Jeff Bye. I manage the Prestone Antifreeze business for the Consumer Products Group of Honeywell International, and I also, as mentioned, represent our industry association through the CSPA. Our business is an automotive after-market business. We also manufacture FRAM filters and Autolite sparkplugs. Our business is headquartered in Danbury, Connecticut. We are part of Honeywell International, which I am sure many of you know is a large, multinational corporation, maybe 120,000 employees, about 60,000 in the United States. A little history: Prestone, the business I manage, is the leading producer in North America and the leading marketer of antifreeze. We sell the product in all 50 States, as well as Canada and Mexico. We sell the product primarily into retail through people like Auto Zone, Advance Auto Parts, and Pep Boys. We also sell through mass merchants, such as Wal-Mart, K-Mart, and a number of smaller outlets. The product is produced in three plants in the United States, in Freehold, New Jersey; Alsip, Illinois; and Torrance, California. We also have a small plant in Mexico City.

We manufacture and the brands we sell, again, primarily to retail, are under the Prestone brand, and then a whole host of store brands and private label brands. We also do some bulk manufacturing for the auto manufacturers, themselves, primarily General Motors, Ford, and Toyota. A little bit about antifreeze that maybe we didn't get completely from Mr. Ackerman. It has been around for over 75 years in a form not unlike it is today and that is primarily with the chemical ethylene glycol in it. Ethylene glycol has some phenomenal properties in terms of lowering the freeze point of water and keeping high temperatures under control, so it makes a perfect coolant in a car's engine. And then again, it has been like that for over 75 years.

In more recent history, antifreeze has been called on to provide some other functions within an engine and primarily, that revolves around corrosion protection of a car's cooling system and heating system. To accomplish that, over the last 20 to 30 years, along with the ethylene glycol, a number of chemical additives have been put into antifreeze, and if you were to buy that gallon of antifreeze today, it would be about 95 percent ethylene glycol and about 5 percent other chemicals. Most of what we do and most of what our chemists do for us and in the industry is work on those other chemicals, that 5 percent. Those are the chemicals that are proprietary, patented formulas that work for corrosion protection. Ethylene glycol is ethylene glycol, and it has its temperature controlling properties.

Ethylene glycol does a great job of controlling temperatures and providing freeze protection, but as you have also heard, it has a down side in that it is highly toxic, especially when ingested by people or pets. To that end, we have, as a company and our industry, taken extensive steps throughout the years to protect people and particularly children: child-proof caps, foil seals, and warning labels. We sponsor poison control centers. We do public service announcements on proper disposal and handling of the antifreeze. Although there haven't been fatalities, there are poisonings that happen periodically by accident with adults and children. We can't say the same for pets, as you pointed out. Mr. Ackerman pointed out, you will find it in the parking lots spilled out of older radiators, people will dispose of it improperly, leave it open in a garage and pets have consumed it and have died from it. To that, the animal rights folks and animal welfare people have, for the past number of years, pushed lawmakers on a local, State and Federal basis to support legislation that requires manufacturers like ourselves to provide and put into our product a bittering agent to discourage animals from drinking the product.

In fact, going back to 1991 up to now, three States have enacted legislation; Oregon being the first, followed by California in 2002, and most recently New Mexico last year. Those States require us to include the product DB in our product to prevent accidental poisonings. In 2004, we partnered with, as an industry, with the Doris Day League to get Federal legislation passed that would accomplish what they are looking for, which is the prevention of poisoning of animals on a broader basis. And what we, as manufacturers, would look for, which is a way to provide that product to all 50 States, but in a way that is sort of within the course of commerce--practical and reasonable and efficient. Because right now there are 11 States that have legislation pending, and that legislation covers a number of plants and a number of locations. Even the bills themselves are not uniform in what they require of the producers, so the bill would provide a uniform benefit to both sides from poisoning and to distribution.

Further, that bill also provides assigned liability to us, as manufacturers of the antifreeze. It holds us responsible for that product which we know and design, antifreeze. We are fully responsible for our product in any way, shape, and form, always have been and always will be, and assigns liability to the producers of bitterant, in this case the producers of DB, for their product and its impact if there is a problem. Because at the end of the day, what we do as an industry is, and what our chemists, what they spend all their time on is analyzing products that go in car's cooling system and the impact of that product on a car's cooling system. And to that end, you know, we are fully responsible for that. We are more than happy to include a product that is not intended for that purpose, if it satisfies the needs of another group. But we are not experts in that product and to that end, that is why we look to have this bill assign liability to those people that are in that realm, which is not where our expertise lies.

And with that, I appreciate the opportunity to speak here and will welcome any questions at the right time. Thank you.

[The prepared statement of Jeffrey Bye follows:]

# PREPARED STATEMENT OF JEFFREY BYE, VICE PRESIDENT, PRESTONE, HONEYWELL INTERNATIONAL, INC., ON BEHALF OF CONSUMER SPECIALTY PRODUCTS ASSOCIATION

#### Introduction

Good afternoon. I am Jeff Bye, Vice President for Prestone, a Honeywell business. Prestone has been the leader in the manufacture, marketing and sale of antifreeze products for over 75 years. I am here representing Honeywell as well as the domestic antifreeze industry, which has been organized by the Consumer Specialty Products Association. We appear before the Committee in support of HR 2567.

Honeywell is a diversified technology and manufacturing leader, serving customers with aerospace products and services; control, sensing and security technologies; automotive products; specialty chemicals; fibers; and electronic materials. Based in Morris Township, New Jersey, Honeywell's shares are traded on the New York Stock Exchange as well as on the London, Chicago and Pacific Stock Exchanges. We are one of the 30 stocks that make up the Dow Jones Industrial Average and we are also a component of the Standard & Poor's 500 Index. The company employs over 120,000 employees, with approximately 60,000 in the United States, and is comprised of four business units: Aerospace, Automation and Control Systems; Specialty Materials, and Transportation Systems. Prestone is part of the Consumer Products Group within the Transportation Systems business unit, with business headquarters in Torrance, California.

#### Prestone Background

Honeywell is the largest manufacturer and supplier of automotive antifreeze in the United States, Canada and Mexico. Its Prestone brand is the most widely recognized and distributed brand of antifreeze in North America. In the United States, our Prestone antifreeze is sold in all 50 states and through virtually all major mass retailers, such as Wal-Mart, and auto retailers, such as Autozone and Advance. In addition, we supply private label antifreeze to most major retailers throughout the nation. We also supply automakers, such as General Motors, Ford and Toyota, for the factory fill of their automobiles in North America.

It may be helpful to understand the origin of antifreeze use in the automotive industry. Originally, motorists drove cars, such as the Ford Model T, without heaters or side and rear windows and, not surprisingly, winter driving was very unpleasant. Later, with the development of car heaters, installation of side and rear windows, and improvements in engines and engine lubricants, motorists drove more comfortably and frequently in winter and demand for engine antifreeze arose. At that time, many compounds were used with water as a form of antifreeze, including honey, sugar, molasses and, the most popular, methyl alcohol. Even methyl alcohol, however, had significant drawbacks including odor and flammability. Motorists were often uncertain about the freezing protection afforded by these fluids.

The antifreeze/coolant business as we know it today began with Prestone brand ethylene glycol antifreeze in 1927. It was pure ethylene glycol in cans and was packaged with charts showing the protection afforded by specific dilutions. The fluid would not evaporate or burn, was relatively odorless and offered many advantages over the substances used earlier by motorists. A few years later, Prestone developed and marketed the first inhibitor in its antifreeze to offer additional protection for the cooling system and to retard rust. In the early 1960s, Ford, General Motors and Chrysler began filling their new cars with a 50% ethylene glycol and 50% water antifreeze/coolant solution, which led to the emergence of antifreeze/coolant as a year-round functional fluid in the automotive industry. Since then, Prestone and other producers of antifreeze/coolant have developed their formulations to provide even better corrosion protection and extend the life of a car's cooling system.

Ethylene glycol, which is a major ingredient of antifreeze, is toxic. For several decades, manufacturers of antifreeze have used foil safety seals and childproof caps to guard against the accidental human ingestion of antifreeze. Prestone provides prominent label warnings about proper use, storage and disposal of antifreeze. We fully comply with all child protection requirements established by the Consumer Products Safety Commission and we are dedicated to continual improvement. In addition, manufacturers have participated in public education and outreach promoting the safe use and storage of antifreeze. During the past ten years, antifreeze manufacturers have supported the American Association of Poison Control Centers in a series of public service announcements entitled "Take Care: Car Fluids, Children and Pets." These public service and other automobile fluids.

Although it is rare that children are accidentally exposed to antifreeze, there are occasions where household pets and other animals are exposed to ethylene glycol products and are injured by ingesting the product. Some animal deaths are likely caused by intentional poisoning, such as a disgruntled person targeting a neighborhood dog that has been barking at night or causing other problems. Other animal fatalities are accidentally caused by antifreeze that has spilled or been carelessly left in improperly secured containers. We and other antifreeze manufacturers sponsor a national poison control center as a resource and service for veterinarians and pet owners. The center is staffed with specially trained veterinary toxicologists available to handle any animal poison-related emergency, 24 hours a day, 365 days a year.

#### Need for a Single Uniform Antifreeze Standard

For several years, the animal welfare community has encouraged local, state and federal lawmakers to pass legislation requiring antifreeze manufacturers to add denatonium benzoate ("DB"), a widely known bittering agent, to their product. The animal welfare community has argued that adding DB to antifreeze would make the product taste bitter, discouraging animals from ingesting the liquid. Their legislative efforts have met with some success, with laws passed in Oregon, California and New Mexico in 1991, 2002 and 2005, respectively.

In December 2004, the antifreeze industry reached out to the Doris Day Animal League to develop consensus federal legislation that would address the safety concerns of the animal rights community. The consensus federal legislation – HR 2567 – would require the addition of DB in antifreeze with the goal of rendering the product unpalatable and deterring children, pets and other animals from accidental poisoning. This federal legislation would create a national standard. Although California, Oregon and New Mexico have passed similar or identical laws, HR 2567's preemption provision would avoid the potential inconsistency and practical difficulty of manufacturers complying with a patchwork of various state and local mandates. At least eleven states have been actively considering similar requirements, including Alabama, Maine, Missouri, Nebraska, Nevada, New Jersey, New York, Ohio, Tennessee, Virginia and Washington, and the trend indicates that additional states will pursue antifreeze bills.

Now is the appropriate time for Congress to establish a national standard. The difficulty of managing compliance with a patchwork of inconsistent state mandates would be significant and would hinder an adequate supply of antifreeze across the country. Further, the additional costs at the manufacturing and distribution levels would ultimately be borne by the American consumer – for a product that is considered a necessity for the proper maintenance of an automobile's engine. A national standard would ensure that the mandate is both uniform and cost effective, while responding to the call for improved antifreeze safety measures. Some states that have passed or considered antifreeze legislation, including New Mexico and Maine, have expressed their desire for

Congress to pass a federal bill because they recognize the appropriateness of a national standard and federal enforcement.

# Liability Provisions

HR 2567 would provide fair responsibility for the antifreeze and DB products by assigning liability between the respective manufacturers. Prestone scientists have developed antifreeze products that we stand behind and are willing to defend. Antifreeze manufacturers, however, do not manufacture or distribute DB. While antifreeze manufacturers are willing to add DB in compliance with a national standard, antifreeze manufacturers should not be exposed to liability for complying with that mandate. The proposed federal legislation would not change the liability of antifreeze manufacturers for their products. Under the legislation, antifreeze manufacturers and distributors are liable for the ethylene glycol antifreeze itself, and DB manufacturers and distributors are liable for their bittering agent.

HR 2567 shares the essential components of the liability provisions within the New Mexico, California and Oregon state laws as well as legislation introduced in the House of Representatives in 2004. Notably, the three state laws and HR 1563, sponsored in the 108<sup>th</sup> Congress by Reps. Gary Ackerman (D-NY) and Dana Rohrabacher (R-CA), all provide some form of liability protection to antifreeze manufacturers for the consequences of DB. Indeed, HR 1563 in the 108<sup>th</sup> Congress was cosponsored by 110 House Democrats and 23 House Republicans.

The 2005 New Mexico law (NM §57-19-38) includes the following liability provisions:

"A manufacturer, packager, distributor, or recycler or seller of engine coolant or antifreeze that is required to contain an aversive or bittering agent pursuant to this section is not liable to any person for personal injury, death, property damage, damage to the environment or natural resources or economic loss that results from the inclusion of denatonium benzoate in engine coolant or antifreeze.

The limitation on liability ... of this section is only applicable if denatonium benzoate is included in engine coolant or antifreeze in the concentrations mandated by this section. The limitation on liability provided ... does not apply to a particular liability to the extent that the cause of that liability is unrelated to the inclusion of denatonium benzoate in engine coolant or antifreeze."

The 2002 California law (Section 17582) includes the following liability provisions: "A manufacturer, distributor, recycler, or seller of an automotive product that is required to contain an aversive agent under this section is not liable to any person for any personal injury, death, or property damage that results from the inclusion of denatonium in ethylene glycol antifreeze."

The 1992 Oregon law (§§431.870 – 915) includes the following liability provisions: "(1) A manufacturer, distributor or seller of a toxic household product that is required to contain an aversive agent ... is not liable to any person for any personal injury, death or property damage that results from the inclusion of the aversive agent in the toxic household product.

(2) The limitation on liability provided by this section is only applicable if the aversive agent is included in the toxic household product in concentrations approved by the Poison Prevention Task Force.

(3) The limitation on liability provided by this section does not apply if the personal injury, death or property results from willful and wanton misconduct by the manufacturer, distributor or seller of the toxic household product."

HR 1563 in the 108<sup>th</sup> Congress included the following liability provisions: "LIABILITY-

(1) LIMITATION- A manufacturer, distributor, recycler, or seller of an automotive product that is required to contain an aversive agent under this section is not liable to any person for any personal injury, death, or property damage that results from the inclusion of denatonium benzoate in ethylene glycol antifreeze, provided that the inclusion of denatonium benzoate is in concentrations mandated by subsection (a).

(2) EXCEPTION FOR WILLFUL MISCONDUCT- The limitation on liability provided by this subsection shall not apply if the personal injury, death, or property damage results from willful or wanton misconduct by the manufacturer, distributor, recycler, or seller of the ethylene glycol antifreeze."

The current House legislation in the 109<sup>th</sup> Congress, HR 2567, includes the following liability provisions:

"Limitation on Liability- (1) Subject to paragraph (2), a manufacturer, processor, distributor, recycler, or seller of an engine coolant or antifreeze that is required to contain an aversive agent... shall not be liable to any person for any personal injury, death, property damage, damage to the environment (including natural resources), or economic loss that results from the inclusion of denatonium benzoate in any engine coolant or antifreeze, provided that the inclusion of denatonium benzoate is present in concentrations mandated...

(2) The limitation on liability provided in this subsection does not apply to a particular liability to the extent that the cause of such liability is unrelated to the inclusion of denatonium benzoate in any engine coolant or antifreeze.

(3) Nothing in this subsection shall be construed to exempt any manufacturer or distributor of denatonium benzoate from any liability related to denatonium benzoate."

In fact, the current version of the federal bill improves upon the bill in the 108<sup>th</sup> Congress by unambiguously establishing the liability responsibilities of antifreeze and denatonium benzoate manufacturers. HR 2567 includes the final provision of the liability section (paragraph (3)) to clarify that the liability protections regarding DB extend only to antifreeze manufacturers, while paragraph (2) explicitly restricts any protections only to the consequences of DB.

#### Alternative Bittering Agents

The three state laws differ in regard to allowing alternative bittering agents beyond DB, and the bill passed by the Senate Commerce Committee in November 2005 differs as well. New Mexico law requires antifreeze manufacturers to specifically add DB as the sole bittering agent to their products. California law specifies DB as an appropriate bittering agent, but allows alternatives to DB if another agent meets the same degree of aversion at the same concentration. Because DB is the only chemical that currently satisfies the legislation's bitterness standard at the specified concentration, California law effectively establishes a mandate requiring manufacturers to use DB to fulfill the state law requirements. Oregon law as passed in 1992 generically called for the addition of an aversive agent, but a 1993 litigation settlement regarding the statute specifies DB as the sole agent at a required concentration.

In November 2005, the Senate Commerce Committee considered the possibility of allowing alternatives to DB, and the Committee passed a bipartisan amendment to allow the Consumer Product Safety Commission (CPSC) to propose an alternative bittering agent if the alternative is as effective as DB as a bitterant, is compatible with motor vehicle engines, and shows no evidence of unreasonable adverse effects on the

environment. The CPSC is the federal agency responsible for regulation and enforcement of federal laws associated with antifreeze and other consumer products.

Prestone and the other domestic antifreeze manufacturers supported the Senate Commerce Committee amendment allowing alternative bittering agents. The CPSC's requirements, however, are important to recognize. Because of DB's unique bittering characteristics, we are able to add a minimal quantity of the additive. Antifreeze manufacturers would have to add more volume of other bittering agents to achieve the same level of discouragement based on odor and/or taste. Another important consideration is the affect of the alternative bittering agent on an automobile. DB has proven to be a safe substance within motor vehicle engines, and alternatives may corrode the engine or impact its functionality.

Prestone and the U.S. antifreeze industry appreciate the deliberative approach that Chairman Gillmor has taken in regard to the development of HR 2567, the Antifreeze Bittering Agent Act of 2005. We are ready to assist the Committee as it considers the legislation, and we will be happy to answer any of the Committee's questions.

MR. GILLMOR. Thank you very much, and we will now go to Mr. Patrice Simms, Natural Resources Defense Council.

MR. SIMMS. Good afternoon, Chairman and members of the committee. My name is Patrice Simms. I am a Senior Project Attorney with the Natural Resources Defense Council, and I thank you very much for asking me here to speak to you today. I also have written comments that I have provided, and I hope that you will accept them.

MR. GILLMOR. Everybody's full written statement will be part of the record.

MR. SIMMS. Thank you very much. I am not going to strictly follow my written comments, but I am going to follow that outline. And I do want to reiterate, at the very beginning, that NRDC is a staunch supporter of strong laws to protect people and the environment, including animal life, both domestic animals and wildlife. More specifically, we support the idea of making antifreeze a safer product to have in the marketplace. We also recognize that one way to do that may be to make antifreeze less palatable, therefore making it less attractive and reducing the number and seriousness of instances of accidental ingestion, particularly, again, among children, pets, and wildlife. That said, unfortunately, NRDC must oppose the bill as it is currently written, and I want to discuss a little bit the outline of our objections to the bill and the basis for those objections.

From NRDC's perspective there are two really critical issues. The first one is one that you have heard mentioned again and again here today, that the bill currently includes a liability waiver for the manufacturers and in fact, apparently for the entire chain, from the antifreeze production all the way through the recycling stage. And this waiver essentially holds harmless this entire industry from injury, whether it is property damage, whether it is physical injury, permanent disability, death, any range in there, as well as environmental harms, including harms that would impair our important natural resources such as drinking water. Second, the bill preempts States from regulating antifreeze bitterants, and you have heard this from a couple of people who have spoken already today States' ability to regulate products that are dangerous to people's health and the environment is incredibly important, and treading on that ability is something that should be avoided. In this case, the ability for States to act is very important as a backstop to any potential injury that might happen down the road, and preempting States from that ability is something that we would strenuously object to.

With respect to the liability waiver, as a matter of general principle, liability waivers are, in our view, not good policy, especially where the underlying requirement, in this case, the requirement for a bittering agent to be added to the market product, is imposed to address a harm that is directly the result of the production and resale of the product itself. That is the reason that the DB, or the other bittering agent, needs to be in the product is because the product is otherwise unacceptably dangerous for the public to have. At least that would presumably be the basis for requiring some regulation to make it safer. And it only makes sense to hold the industry that benefits from having that product, that highly toxic product, in the marketplace, responsible not only for instances of harm caused by the product itself, but instances of harm caused by additives that are necessary to make that product acceptably safe, and for that reason, the idea of a liability waiver is particularly objectionable in this case.

I would note that the public always carries its share of the risk, because the public stands at the frontline whenever any injury does occur, and it is fundamentally unfair, in this situation, to insist that the public continuing to carry its risk and to not require the industry that is benefiting from the product to also carry its risk of possible harm in the future.

Now I would note we have heard a number of things today. I would like to emphasize one of the things that we have heard come up again and again, and that is that we know very little about the impact of DB in the environment, and that is critically important, and we have included as an attachment to NRDC's testimony some summary of the same studies that people have spoken about today. And the fact that we know very little means, in our view, it is very unwise at this point to suggest that we ought to be waiving liability for this product. Similarly, in our view, it makes very little sense at this point to specifically identify DB as the only possible bitterant to be added to antifreeze to make it a safer product. From what we are aware, there is very little reason for that limitation and in fact, the primary function of that limitation is to set up a justification for a liability waiver.

MR. GILLMOR. I don't want to assume, but we are trying to stay within our time constraints.

MR. SIMMS. Okay.

Very well. So I will note only one other point and that is something that confuses me a little bit here, and that is that there has been argument back and forth about whether or not DB is dangerous or not. If it is dangerous, it is unwise to waive liability. If it is not dangerous, why is the application of liability to the industry problematic? It would be, if you accept that factual basis, it is a negligible risk and so why is that a problem? And from our view, the liability waiver and the preemption of State authority, any way you look at the facts underlying this particular bill, are inappropriate. Thank you very much for allowing me to speak.

[The prepared statement of Patrice L. Simms follows:]

# PREPARED STATEMENT OF PATRICE L. SIMMS, SENIOR PROJECT ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL

Mr. Chairman, and Honorable Members of the Committee, thank you for this opportunity to speak with you today about H.R. 2567, the Antifreeze Bittering Act of 2005.

Allow me to start by saying that NRDC is a staunch supporter of strong laws that protect the health and wellbeing of people and animals. At its core, the intent of this bill is certainly positive – to protect the health and wellbeing of children, household pets, and wildlife that may be exposed to ethylene glycol (the highly toxic chemical commonly used as automobile antifreeze). We also commend organizations like the Doris Day Animal League for pursuing this worthy cause, and the sponsors and supporters of this bill for making this important issue a priority.

Unfortunately, NRDC must oppose this bill as it is currently written. As a general matter, we do not oppose, and in some cases have specifically recognized the value of bitterants as one means of reducing the number and severity of exposures to toxic chemicals. However, the inclusion of a sweeping liability waiver in H.R. 2567, that would give antifreeze manufacturers, processors, distributors, recyclers and retailers, a get-out-of-jail-free card with respect to any harm that a bittering agent might cause in the future, is simply unpalatable. This "free pass" would apply not only in instances where the bittering agent causes damage to motor vehicle equipment, but also where it directly harms people (by causing sickness or death) or where it causes environmental damage (including impairment of natural resources). Significantly, the waiver also includes no exceptions for harm that results from gross negligence or willful misconduct.

Additionally, the bill includes a provision that preempts States from regulating, in any way and for any reason, antifreeze bitterants (except to the extent that the State regulations are identical to the provisions of H.R. 2567). Preempting State authority to adopt stricter rules than those required at the federal level is rarely a good policy, and in this case it is both unnecessary and unwise.

While we support the regulatory objective of making antifreeze a safer product, including, as one option, a bittering agent requirement in order to reduce the chances of poisoning children, pets, and wildlife, we do not understand why this bill mandates the use of a specific bitterant and then provides a liability waiver. We would urge that the legislation simply require the use of an effective bitterant that will prevent children and

pets from consuming this otherwise sweet-tasting toxic product, and allow the industry to determine what bitterant might be most safe and effective. In our view, it is inappropriate to assign the risks that denotonium benzoate (DB) or another bitterant may pose to the public and the environment, rather than to the industry that reaps the economic benefit from sale of a toxic product that requires a bitterant to be safe.

The mandate to use DB exclusively appears to serve no purpose other than to create a justification for also including a liability waiver -a waiver that takes important protections away from the American people. In fact, allowing flexibility in the use of bitterants would make it easier for industry to respond to any problems that might arise with a particular chemical, or to shift to a more effective, more readily available, safer, less expensive, or otherwise more appropriate chemical if one were to emerge.

There is nothing inappropriate about requiring that the antifreeze industry to make a product that is as safe at it can be – by appropriately addressing the attractiveness and availability of its product to children and animals (including, e.g., taste, color and safety packaging) and by taking responsibility for the toxicity and adverse health and environmental impacts of all the product's ingredients (including impacts resulting from the use of bitterants).

The bill's preemption of State authority to regulate antifreeze bitterants is also troubling. NRDC has a long history of opposing attempts to preempt more stringent State law. In general, in our view, it makes little sense to limit the tools available to States in their front line battles to protect their citizens and respond to public health or environmental hazards. Precluding States from adopting laws more stringent than, or in addition to, federal law prevents advances in public health and environmental protection and leaves people more vulnerable.

While we recognize the importance of the issue that the bill sponsors are attempting to address, and we hope that Congress is able to pass a strong bill that makes antifreeze a safer product, for the reasons I have outlined here, NRDC cannot support H.R. 2567.

Once again, thank you for giving me the opportunity to address this committee today and explain to you NRDC's position on this bill.

MR. GILLMOR. Thank you. And next is Dr. Melinda Eyrich, Coowner of Urgent Care Veterinarian Hospital. Dr. Eyrich.

DR. EYRICH. Thank you, Mr. Chairman, for the opportunity to speak here before this committee today. I have been a veterinarian for approximately 15 years, focusing on emergency medicine for that past seven years. I am a member of the AVA, the American Veterinary Association, and I also have a letter from the AVA to submit to record today, with me.

When I was asked to speak here today, I was asked to reflect on specific cases of antifreeze poisoning that I have seen over the years as an emergency veterinarian, and there are way too many, to be quite honest with you. But one case specifically came to my mind, and I would like you to indulge me to relay that case to you today.

An 8 year-old male golden retriever was presented into my clinic one evening in the fall of the year. He was unable to lift his head, but being a golden retriever he could still just very weakly wag his tail as he laid on the table. His lab values showed that he was in kidney failure, and the test for ethylene glycol, or antifreeze, in his blood was extremely positive.

And I have to tell you, on the other side of this exam room table from me was a family with 2 young boys, approximately the age of 10 and 12, and they were in tears over their sick friend, and I gave his family a very poor prognosis for this dog's recovery. At that time, I also discussed with them the extreme expense involved in trying to treat this animal. The pharmaceutical that we use to treat antifreeze poisoning is called Antizol, and it is approximately \$300 a vial. It is an extreme financial hardship for most families, and in most families the cost of treating this disease is actually prohibitive. But this family decided, because of the extreme worth to this family that this dog was, that they were going to go ahead and try to treat this animal. So over the next 3 days we tried to save this dog, and in the course of visits with his family, I got to know them and I got to know the relationship they had with this dog. This animal was a gift. He had played fetch with the boys, he had gone swimming with them in the summertime, he had slept on one of the boys' beds every night, faithfully, and he waited for them to come home. But at the end of the 3 days, we were not able to save this dog and the decision was make to humanely euthanize him, in the face of worsening lab work

But as we sat around this dog after we had euthanized him, the younger of the two boys looked at me and he asked me a question and he said, "Why does antifreeze kill dogs?" And I started with a medical explanation of why antifreeze kills dogs. I said, "It causes kidney failure and sometimes we can't reverse that process." But part way through my explanation, he interrupted me and he said, "No. What I want to know is, why do we have a substance around so commonly that kills dogs?" His statement to me was everybody has it. And then I tried to explain to him that it was not the intention of antifreeze to kill dogs. It is the intention of antifreeze to help car engines. And his response to me was, that doesn't make it right. And he was correct, it doesn't make it right.

As I looked at my own two children before I left today, I realized that there are enough things that are difficult to explain to children in this world, that if we have a chance to change something that is very difficult to explain to them, then maybe we should act and try to do that. This seems like a very simple solution to a very deadly problem.

Antifreeze, for dogs, is not only deadly, but it is attractive. It has a sweet taste, as you have already learned today. I can tell you, anecdotally, dogs do not like bitter tastes. Also, this toxicity, as I have already mentioned, is also not only emotionally taxing for families, but it is financially taxing for families. I am fortunate. I live in the State of New Mexico. We already have a law in place requiring a bitterant added to antifreeze. I would like to see help for my peers in the other 47 States, as it sounds like they need help with this issue. Thank you for your time.

# [The prepared statement of Dr. Melinda Eyrich follows:]

# PREPARED STATEMENT OF DR. MELINDA EYRICH, DVM, CO-OWNER, URGENT CARE VETERINARIAN HOSPITAL

Thank you Mr. Chairman for the opportunity to testify before the committee today.

My name is Dr. Melinda Eyrich; I have been a veterinarian for the past 15 years, focusing on emergency medicine for the past 7 years. I am the owner of Urgent Care Veterinary Hospital in Albuquerque, New Mexico.

When I was asked to speak today, I was also asked to reflect on specific cases of antifreeze poisoning. One case in particular jumped into my mind. An 8 year old male Golden Retriever. He presented in the fall of the year, unable to raise his head but he could still weakly wag his tail. He was in kidney failure. The test for the presence of ethylene glycol in his system was strongly positive.

On the other side of the exam table from me were two young boys, in tears, over their sick friend. Their approximate ages were 10 and 12 years old. I gave the family a very poor prognosis for recovery. The decision was made to try and save this important family member. As we worked to save him over the next three days, the two boys recalled countless stories of how he had shared their youth. In their young eyes, This Golden Retriever had shared their entire lives. He had played fetch, swam and slept on their beds. This friend had waited loyally for them to return on the bus at the end of each day.

The most effective treatment for ethylene glycol poisoning is very expensive. I am not able to mark up the drug we use because, at approximately three hundred dollars a vial, the expense is prohibitive to most families. At the end of three tear-filled and heart wrenching days—in the face of worsening lab results—we could not save this family member.

These boys witnessed a horrible painful death until the difficult decision was made to euthanize their friend. When the younger boy asked why antifreeze kills dogs, I initially started to explain the clinical reason for the kidney failure it causes. Part way into my explanation, he interrupted me and reworded his question so that I understood that what he was really asking is why do we have something so commonly around that kills dogs. I remember him saying "everyone has it". I tried to explain that was not its intended use and that his friend's death was an accident. He replied "that does not make it all right."

He was correct. The events of this world can be hard enough to explain to children. If we have a chance to lessen some of the wrongs, and make them right, we should act.

The addition of an agent to make antifreeze taste bitter appears to be a practical simple solution, to a very deadly killer. This type of toxicity is not only emotionally taxing for families but a financial hardship as well – usually in the face of a guarded prognosis. I would love to be able to never dread the change of seasons, when well-meaning people change their antifreeze and do not dispose of it safely. It would be a celebration to never lose a friend to something that could be made preventable.

Thank you.

MR. GILLMOR. Thank you, Doctor. Mr. Tom Bonacquisti.

MR. BONACQUISTI. Bonacquisti.

MR. GILLMOR. Okay. Good. The Director of Water Quality and Production, Fairfax County Water Authority, and he is testifying on behalf of the American Water Works Association. MR. BONACQUISTI. Good afternoon, Mr. Chairman and members of the subcommittee. I am Tom Bonacquisti, Director of Water Quality and Production for the Fairfax County Water Authority in Fairfax County, Virginia. I am here on behalf of the American Water Works Association, or AWWA. AWWA commends you for holding this hearing and appreciates the opportunity to present its views on H.R. 2567, the Antifreeze Bittering Act of 2005.

Founded in 1881, AWWA is the world's largest and oldest scientific and educational association representing drinking water supply professionals. Our membership, over 57,000 strong, is comprised of administrators, utility operators, professional engineers, contractors, manufacturers, scientists, professors, health professionals, and ordinary citizens. The association's membership includes over 4,800 utilities that provide over 80 percent of this Nation's drinking water. AWWA and its members are dedicated to providing safe, reliable drinking water to the American people.

AWWA commends efforts to protect children and animals from the dangers of ingesting antifreeze. We support efforts to find a solution to prevent the tragedies that occur when children or animals ingest toxic doses of antifreeze. As an association of professionals dedicated to protecting public health, we can relate to the desire to ensure that children and animals don't accidentally ingest a poisonous compound. AWWA's members work everyday to ensure that millions of Americans have safe, high-quality water. We understand that if antifreeze had a bitter taste, some needless suffering and expense might be avoided.

In our statement today, we will not comment on how best to achieve the goal of protecting our children and pets from antifreeze poisoning, or which bittering agent to use. Those issues lie outside of our area of expertise. We have serious reservations about statutorily mandating a specific bittering agent and specific concentrations of that agent. We generally believe those kinds of decisions should be left to the regulatory process, in which all available scientific data can be examined and decisions can be made with opportunity for public review and comment and outside an overtly political process.

We also have very serious concerns about language in the bill that waives the liability of any manufacturer, processor, seller, or recycler of antifreeze containing the prescribed adversive agent from any damages arising from natural resource or environmental damages. This provision is unwise, unsound, and unfair and should be removed from the bill.

In this statement, I will primarily address the liability issue, which is our chief concern with the bill. H.R. 2567 requires the use of denatonium benzoate, DB, as a bittering agent for antifreeze. Little is known about the environmental fate and transport of DB. The material safety data sheet for commercial formulations of DB are not helpful on this matter, as they contain little or no data on the fate and transport of this agent. According to manufacturers, DB is biodegradable and is not known to bioaccumulate. However, studies by other researchers have found that the denatonium ion does not biodegrade during treatment in typical wastewater treatment plants. Some research suggests that to the extent degradation does occur, it is primarily the result of the breakdown of benzoate and that the denatonium ion responsible for the adversive taste of the compound is not easily biodegradable.

Studies also suggest that DB does not adhere to soil, but rather stays in and travels with the groundwater. We believe it is reasonable to expect contamination problems as DB accumulates in the groundwater supplies. Given the extreme bitter properties of DB, it appears that tiny amounts of the chemical could render drinking water supplies bitter and unpalatable. One manufacturer's material safety data sheet states that in cases of accidental release, DB is to be kept out of water supplies and sewers. Given the conflicting and inconclusive data on the fate and transport of DB, particularly in water, it would be very imprudent to provide far-reaching liability immunity to companies making or handling antifreeze containing this chemical or another other adversive agent.

A liability waiver is of particular concern because sooner or later, somewhere, and perhaps in many places, contamination of drinking water supplies is likely to occur. When that happens, drinking water utilities will be forced to treat or remove this compound from the water they deliver to their customers. Our customers will not accept the taste of antifreeze in their tap water. When contamination occurs, drinking water utilities will be forced to change or add treatment or removal to get DB out of the drinking water. In severe cases, this could even require the abandonment of water supplies and the development of new sources. Increasingly, in many areas of the country, such new sources are unavailable. Whatever a drinking water utility is forced to do, it is all but certain to increase the cost of water in that community, perhaps significantly. The question will become, who should fairly bear that cost?

History is replete with examples of the unintended consequences of measures adopted to obtain laudable goals. Perchlorate was added to munitions to make them more stable. However, perchlorate is now found to be contaminating drinking water supplies. MTBE, or methyl tertiary butyl ether, was added to motor fuels to reduce air pollution. However, MTBE contaminated drinking water supplies in many areas of the country, and even minute quantities of MTBE made drinking water unpalatable. The cost of cleaning up MTBE-contaminated drinking water supplies is conservatively estimated at billions of dollars.

No one can know what the cost of removing DB from drinking water supplies might be, and I am not asserting that it would be billions of dollars. Some contamination of water supplies by DB and some increased cost of treatment or removal, perhaps significant, is all but inevitable. It is also important to remember that antifreeze is used in large volumes.

I would like to say, in conclusion, AWWA recommends a regulatory rather than a legislative process to identify an adverse agent for antifreeze. We strongly oppose the limitation on liability provisions of H.R. 2567 and strongly recommend that liability provisions be deleted from this bill. AWWA and its members thank you for holding this hearing concerning H.R. 2567, and thank you for considering our views.

[The prepared statement of Tom Bonacquisti follows:]

PREPARED STATEMENT OF TOM BONACQUISTI, DIRECTOR OF WATER QUALITY AND PRODUCTION, FAIRFAX COUNTY WATER AUTHORITY, ON BEHALF OF AMERICAN WATER WORKS ASSOCIATION

# SUMMARY OF MAJOR POINTS

- 1. AWWA commends efforts to protect children and animals from the dangers of ingesting antifreeze.
- 2. AWWA recommends a regulatory rather than a legislative process to identify an aversive agent for antifreeze.
- 3. AWWA strongly opposes the Limitation on Liability provisions of H.R. 2567, and strongly recommends that liability provisions be deleted from the bill.

### **INTRODUCTION**

Good morning Mr. Chairman. I am Tom Bonacquisti, Director of Water Quality and Production for the Fairfax County Water Authority in Fairfax, Virginia. I am here on behalf of the American Water Works Association (AWWA). AWWA commends you for holding this hearing and appreciates the opportunity to present its views on H.R. 2567 – The Antifreeze Bittering Act of 2005.

Founded in 1881, AWWA is the world's largest and oldest scientific and educational association representing drinking water supply professionals. Our membership, over 57,000 strong, is comprised of administrators, utility operators, professional engineers, contractors, manufacturers, scientists, professors, health professionals, and ordinary citizens. The association's membership includes over 4,800 utilities that provide over 80 percent of the nation's drinking water. AWWA and its members are dedicated to providing safe, reliable drinking water to the American people.

# ANTIFREEZE POISONING IN CHILDREN AND PETS

AWWA commends your committee's efforts to protect children and animals from the dangers of ingesting antifreeze. We support efforts to find a solution to prevent the tragedies that occur when children or animals ingest toxic doses of antifreeze. As an association of professionals dedicated to protecting public health, we can relate to the desire to ensure that children and animals don't accidentally ingest a poisonous compound. AWWA's members work every day to ensure that millions of Americans have safe, high quality water. We understand that if antifreeze had a bitter taste, some needless suffering and expense might be avoided.

In our statement today, we will not comment on how best to achieve the goal of protecting our children and pets from antifreeze poisoning or which bittering agent to use. Those issues lie outside our area of expertise. However, we do have serious reservations about statutorily mandating a specific bittering agent and specific concentrations of that agent. We generally believe those kinds of decisions should be left to the regulatory process in which all available scientific data can be examined and decisions can be made with opportunity for public review and comment outside an overtly political process.

We also have very serious concerns about language in the bill that waives the liability of any manufacturer, processor, seller, or recycler of antifreeze containing the prescribed aversive agent from any damages arising from natural resource or environmental damages. This provision is unwise, unsound, and unfair, and should be removed from the bill. In this statement, I will primarily address the liability issue, which is our chief concern with the bill.

# **LIMITATION ON LIABILITY**

H.R. 2567 requires the use of denatonium benzoate (DB) as a bittering agent for antifreeze. Little is known about the environmental fate and transport of DB. The Material Safety Data Sheet (MSDS) for commercial formulations of DB are not helpful on this matter as they contain little or no data on the fate and transport of this agent. According to the manufacturers, DB is biodegradable and is not known to bioaccumulate. However, studies by other researchers have found that the denatonium ion does not biodegrade during treatment in a typical wastewater treatment plant. Moreover, some research suggests that to the extent degradation does occur, it is primarily the result of the breakdown of benzoate and that the denatonium ion, responsible for the aversive taste of the compound, is not easily biodegradable.

Studies also suggest that DB does not adhere to soil, but rather stays in and travels with the ground water. We believe it is reasonable to expect contamination problems as DB accumulates in the groundwater supplies. Given the extreme bitter properties of DB, it appears that tiny amounts of the chemical could render drinking water supplies bitter and unpalatable. One manufacturer's Material Safety Data Sheet states that in cases of accidental release, DB is to be kept out of water supplies and sewers.

Given the conflicting and inconclusive data on the fate and transport of DB, particularly in water, it would be very imprudent to provide far-reaching liability immunity to companies making or handling antifreeze containing this chemical or any other aversive agent.

A liability waiver is of particular concern because sooner or later, somewhere, and perhaps in many places, contamination of drinking water supplies is likely to occur. When that happens, drinking water utilities will be forced to treat or remove this compound from the water they deliver to their customers. Our customers will not accept the taste of antifreeze in their tap water.

When contamination occurs, drinking water utilities will be forced to change or add treatment or removal to get DB out of the drinking water. In severe cases, this could even require the abandonment of water supplies and the development of new sources. Increasingly, in many areas of the country such new sources are unavailable. Whatever a drinking water utility is forced to do, it is all but certain to increase the cost of the water in that community, perhaps significantly. The question will become, who should fairly bear that cost?

History is replete with examples of the unintended consequences of measures adopted to attain laudable goals. Perchlorate was added to munitions to make them more stable; however, perchlorate is now found to be contaminating drinking water supplies. MTBE (methyl tertiary butyl ether) was added to motor fuels to reduce air pollution; however MTBE contaminated drinking water supplies in many areas of the country, and even minute quantities of MTBE made drinking water unpalatable. The cost of cleaning up MTBE-contaminated drinking water supplies is conservatively estimated at billions of dollars.

No one can know what the cost of removing DB from drinking water supplies might be, and I am not asserting that it would be billions of dollars. However, some contamination of water supplies by DB and some increased cost of treatment or removal, perhaps significant, is all but inevitable. It is also important to remember that antifreeze is used in large volumes in many industrial applications, such as airplane de-icing, and that large releases and widespread contamination of water supplies are possible.

Informed by the MTBE experience, we should seek to avoid DB becoming the problem that MTBE became. The impact of even small releases of DB on drinking water supplies is unknown. With a widespread mandate for the use of DB in antifreeze, the incidence of contaminated drinking water supplies can only increase. If this happens, it would be no more fair to excuse the companies making or handling antifreeze from liability than it would be to mandate that they be always liable. The question of liability is and should remain a decision that is made based on the facts of particular cases.

#### **CONCLUSION**

In conclusion, AWWA recommends a regulatory rather than a legislative process to identify an aversive agent for antifreeze, strongly opposes the Limitation on Liability provisions of H.R. 2567, and strongly recommends that liability provisions be deleted from this bill.

AWWA and its members thank you for holding this hearing concerning H.R. 2567 -The Antifreeze Bittering Act of 2005. AWWA. And thank for you considering our views. We will be pleased to answer any questions or provide additional material for the committee.

MR. GILLMOR. Thank you. Sarah Amundson, Deputy and Legislative Director of the Doris Day Animal League.

MS. AMUNDSON. Thank you, Mr. Chairman, and also to Ranking Member Solis, for this opportunity to testify in support of the Antifreeze Bittering Act. I am Sarah Amundson, the Legislative Director with the Doris Day Animal League, and I also want to express our genuine thanks to Representatives Ackerman, Rohrabacher, and Wilson for their leadership on this issue. Do keep in mind that there are more than 58 million homes in this country that have pets. We are a Nation of pet lovers, and the very thought of having 90,000 of our companion animals ingest antifreeze and the majority of them die, on an annul basis, is simply unacceptable. We certainly recognize that there are three States, all three of which we have had a hand in moving legislation in, that currently have this statutory provision on their books. I want to remind folks that all three of those States also have liability provisions in them. So much information has been covered, both through the wonderful Member statements that were given with the opening of the hearing, and also the folks who have testified. I would like to go straight to some of the considerations that have been raised, in the hope that we can address some of these concerns.

First of all, the Doris Day Animal League would by no means advocate for the addition of DB in antifreeze as the panacea to this genuine problem. For obvious reasons we are careful to tell consumers and pet lovers that they need to ensure that antifreeze is properly disposed of, properly stored, and that the industry's efforts to ensure there are child safety caps and foils on the tops of those containers are measures of protecting pets. But what we do know is that animals are actually chewing through those containers, which means they are ingesting antifreeze, not only from spills on driveways, but also through those containers, and that means we need another tool in the toolbox. That is the additional of denatonium benzoate in the antifreeze. We did advocate strongly in 2002, in California, for a very similar statute. We have the support of the American Academy of Pediatrics, the California Integrated Waste Management Board, and yes, folks, the Sierra Club, in that endeavor. In that situation, we were very pleased to have taken an active role, but clearly, as Congressman Ackerman demonstrated, he wants to prevent his colleagues in New York from driving to New Jersey and exposing pets and children to antifreeze poisonings. For that reason, we have got to have a uniform standard, and obviously, the only way to regulate interstate commerce in this country is through a Federal law.

We are an animal protection organization, which means we are necessarily committed to environmental protection. What that means is, we have done a grave analysis of what is known about DB, the information that is in the risk assessment profile, consideration for the fact that it is between 30 and 50 parts per million that actually goes into antifreeze in this country to render it bitter, revisit the fact that it only takes 7,000 gallons to render all of the antifreeze covered by this bill in this country bitter. And I just want to make a valuable point here. There has been some misinformation. This bill will only cover the consumer market where we have seen the grave nature of this problem. It does not cover industrial or commercial uses, which means plane deicing is not covered by this bill. We are talking about consumers here.

In addition, there have been grave concerns raised about the liability waiver. As an animal organization concerned about environmental protection, I can say that there is no possible way we would support a blanket sort of liability waiver, and it doesn't exist in this bill. For obvious reasons, I am sure if you asked Mr. Bye here, he would state that whether it is Superfund, RCRA, or any of the other existing environmental statutes in this country, he knows for a fact that they will still be responsible for cleanup for ethylene glycol antifreeze.

Let us get to the volume issue again. DB is not handled, stored, or used in the same sort of volume as the additive MTBE in this country, and I think Congressman Ackerman did a wonderful job of illustrating the nature of 80 million gallons, on a daily basis, of MTBE versus 7,000 gallons for the entire product of antifreeze covered under the bill, on an annual basis. I wish Congressman Ackerman, with his illustrative points, had taken that cup of denatonium benzoate and showed us just how little of that cup would go into that one-gallon containing, because at 30 to 50 parts per million, you are probably talking about the tip of my finger. That is how little DB would go into a single container.

You know, a lot of concerns have been raised today, and in other situations, with regard to water quality. Today, I want to introduce into the record, with the Chairman's permission, a letter we have received from the California State Water Resources Control Board, appointed by the Governor, stating that, "Even though it is regarded as the bitterest known substance to date, we are unaware of adverse impacts to California's water supplies arising from the use of denatonium benzoate in antifreeze and a variety of other products."

Further to that point, I want to note that this statute has been on the books in the State of Oregon since 1993, and I have a direct quote from a Maine environmental protection report from their State toxicologist. "No incidents of drinking water well contamination or groundwater contamination or bad tasting water due to denatonium benzoate have become known." And of course, Ranking Member Solis referred to the California Integrated Waste Management report that found that DB readily biodegrades and its transport is attenuated in soil.

We have also had a number of concerns raised about the efficacy of DB, and I would like us to take into consideration a weight-of-evidence approach, which is what we often do with chemicals. If EPA is demonstrating what they know about the risk profile, on the basis of the testimony presented here today, it seems to me that much of the criticism about the efficacy of DB has come from a 2004 review of the Oregon Poison Control Center records of pediatric poisonings. I want to point out two quick things here. First and foremost, the majority of problems we have in this country of ethylene glycol poisoning are household pets. There is no reporting requirement for household pet ingestions or deaths in Oregon, so the issue was not even considered. When it comes to efficacy, we have definitely got to take that issue to heart.

The survey also measured exposures, but didn't measure the level of DB in products consumed. A 1996 Oregon study, after the bill was

implemented, did a study of the measurement of DB in the products that were regulated and there were some that had no detectable amounts.

MR. GILLMOR. We will have to wrap up pretty quickly.

Ms. AMUNDSON. Yes, sir. Efficacy has also been studied by EPA. When you consider rodenticides and the previous requirement to ensure both dyes and bittering agents were included in rodenticides, EPA did a review of the scientific data and considered it the bitterest substance known to man. It did not compromise the value of the rodenticides, and the conclusion was that it also prevented children's exposure or children's ingestions of that product. Antifreeze poisonings cause animal suffering and great death. We have a solution here for pennies per gallon, and together, we can find a way to mark this bill up and move it forward, and really address the 90,000 deaths that we are seeing each year. Thank you, Mr. Chairman.

[The prepared statement of Sarah Amundson follows:]

# PREPARED STATEMENT OF SARAH AMUNDSON, DEPUTY AND LEGISLATIVE DIRECTOR, DORIS DAY ANIMAL LEAGUE

Good afternoon. Thank you Mr. Chairman and members of the Subcommittee for the opportunity to testify today in support of the *Antifreeze Bittering Act*. I am Sara Amundson, Legislative Director for the Doris Day Animal League (DDAL). DDAL has 350,000 members and supporters nationwide who strongly support H.R. 2567. The organization was founded in 1987 to promote the protection of animals through legislative advocacy in the states and on the federal level. DDAL is grateful to Representatives Ackerman, Rohrabacher, and Wilson for their leadership on H.R. 2567, a bill with the ultimate goal of better protecting animals and children from a common household hazard.

This bill enjoys broad support from an unlikely coalition of animal advocacy organizations, public health organizations, and the antifreeze industry. In addition to DDAL, these supporters include the American Humane Association, The Humane Society of the United States, the Society for Animal Protective Legislation, Honeywell and all U.S. antifreeze manufacturers, the Consumer Specialty Products Association, the American Academy of Pediatrics, the American Veterinary Medical Association, and the Pet Food Institute.

## Animals and Children are Exposed to Antifreeze

For the past fifteen years, the DDAL has been tracking ingestions of antifreeze by pets and wildlife. Poisoning occurs with this product because it is often inadvertently spilled in our driveways or left in open containers in our garages by automotive "do-it-yourselfers." In addition, a neighbor wishing to rid himself of a barking dog or wandering cat may deliberately bait a pet, instigating a cruel solution to a neighborhood squabble.

Because it is colorful and has a sweet taste, animals and children are drawn to it. Animals may quickly ingest a lethal amount. One teaspoonful of ethylene glycol antifreeze can kill a cat. As little as one to two tablespoonfuls can kill a 100-pound dog. One survey found that two out of three veterinarians see at least one accidental ethylene glycol poisoning each year. The Washington State School of Veterinary Medicine places the annual number of dog and cat antifreeze poisonings at approximately 10,000; however, a 1996 "study of small practice veterinarians throughout the United States found that more than 90,000 dogs and cats die each year from ingesting ethylene glycol antifreeze.<sup>11</sup> Unfortunately, the symptoms of poisoning can be misleading, causing the pet lover to think the animal is merely sleepy until renal failure causes death.

Moreover, according to statistics compiled by the American Association of Poison Control Centers, more than 1,300 children ingest antifreeze each year. The U.S. National Library of Medicine Toxicology Data Network states that the minimum lethal dose for a 150-pound male is 4 ounces, which means it takes far less to kill a child. While records indicate that accidental ingestion by children is caught early enough to prevent death, not all human victims recover because not all ingestions are accidental. Ethylene glycol antifreeze is also used in murders and suicides.

#### Denatonium benzoate

The good news is that, unlike many of the issues we grapple with, this one has a ready solution. DDAL certainly considers safety caps, seals, and public education necessary. However, three states and several other countries have chosen to employ an additional tool, which is requiring the addition of denatonium benzoate (DB) to antifreeze that is sold directly to the consumer.

Denatonium benzoate is one of the bitterest substances known and available to us. In 1963, the Food and Drug Administration (FDA) approved the addition of DB to cosmetic and toiletry products, including nail polish, hair spray, and cleaners, as a safety mechanism to deter children from ingesting them. The U.S. Bureau of Alcohol, Tobacco, Firearms and Explosives (27 CFR 21.76) currently requires that all industrial alcohol-based products contain a bittering agent and specifically requires the use of DB in certain products as a denaturant, making the product unpalatable. The addition of the bitterant has not compromised the usefulness of the products.

Requiring the addition of DB to ethylene glycol antifreeze destined for the consumer retail market has the potential to save thousands of animal lives and prevent hundreds of children from being sent to emergency rooms each year. DDAL strongly urges your support of this small, common-sense measure, literally costing pennies per gallon, to achieve significant, beneficial results.

#### **California State Law**

The Doris Day Animal League has a long history of lobbying in support of state legislation to require the addition of denatonium benzoate to make antifreeze unpalatable to both animals and children. In 1993, in response to concerns from veterinary emergency rooms, DDAL members who had lost a beloved pet, the death of a California condor, and the startling statistics on children gathered annually by the American Association of Poison Control Centers, we successfully lobbied the California legislature to require the addition of denatonium benzoate to antifreeze and coolant products. In spite of significant opposition mounted by the manufacturers of antifreeze, the bills passed with overwhelming votes in both the California Assembly and Senate. Unfortunately, the governor vetoed the bill.

Then in 2000, after losing her family's beloved dog Angus to antifreeze poisoning, Californian Lauren Ward began researching the solution to her family's tragedy. She contacted her state legislators to demand to know why the simple addition of DB to antifreeze to help prevent these unnecessary deaths wasn't required by the state. Fortunately, her assemblyman agreed to introduce a bill to require the bitterant be added.

Our research in support of the California bill demonstrated that in the ten years that had passed, despite the voluntary efforts by the antifreeze industry to educate the public, large numbers of animals were still being poisoned from ingesting antifreeze. In 2001, 13 California veterinary clinics reported 136 cases of antifreeze poisoning with 107

<sup>&</sup>lt;sup>1</sup> Petition published in Fed. Reg. v.63, #27, Feb. 10, 1998, p.6693.

deaths. Antifreeze poisoning continued to send many children to the hospital. Working with Lauren Ward and members of the California State Senate and Assembly, we lobbied again for passage of an antifreeze bittering bill. The California Medical Association, American Academy of Pediatrics, California Veterinary Medical Association and the California Integrated Waste Management Board all supported the legislation. Over the objections of the antifreeze industry, the bill passed and was signed into law in 2002.

Subsequently, we have worked with legislators in several other states in support of bills to require the addition of denatonium benzoate to antifreeze. Last year, New Mexico became the third state to pass such a bill into law. And that language is identical to the federal bill before you today.

DDAL strongly supports the pursuit of progressive state policies. However, because of the nature of commerce in this country and because these poisonings occur regardless of state lines, it is imperative to pass a federal bill to ensure that the goal of reducing antifreeze poisonings is realized. It is important to extend to each child and every animal the extra layer of protection that these states have so wisely adopted. This can be accomplished in a timely and sensible manner only through federal action. A product marketed and distributed on a national basis should have a national standard to meet.

Moreover, the absence of a federal law undermines the effectiveness of existing state laws: The ease of interstate transportation necessitates a uniform policy to prevent antifreeze spills in California from cars driving into the state from Nevada. It is impossible to judge the effectiveness of these new state laws based on the interstate nature of the problem. In fact, the U.S. Conference of Mayors, at its 2004 annual meeting, passed a resolution urging Congress to "help cities protect children and animals by enacting legislation to require denatonium benzoate as an additive to antifreeze that contains ethylene glycol...."

## **Concerns and Questions**

We would like to address and, we hope, allay, some of the concerns about this legislation that have been raised.

First and foremost, comparisons have been made between this legislation and the methyl tertiary butyl ether (MTBE) issue, but there are significant and meaningful differences between the two.

- Contrary to characterizations that have been made, there is no blanket liability waiver in the bill before you today. While the MTBE liability language would also have extended to MTBE manufacturers, H.R. 2567 does exactly the opposite: It holds the manufacturers of antifreeze and of DB liable for their respective products, without limit. All three state laws (California, New Mexico and Oregon) include some form of liability protection for antifreeze manufacturers. H.R. 2567 goes a step further than California's and Oregon's laws by establishing "assigned liability" under which antifreeze manufacturers and denatonium benzoate manufacturers are liable for any problems that arise from the use of their respective product. DDAL would not support legislation that exempts manufacturers from liability for their products.
- In 1999, MTBE use amounted to 8.4 million gallons PER DAY (3 billion+gallonsper year), whereas approximately 7,000 gallons annually of DB will be needed to bitter the antifreeze covered by the legislation (i.e., 157 million gallons). According to a report commissioned by the Maine legislature: "One gallon of reformulated gasoline, if spilled, would release a mass of 308g of MTBE to the environment. It would take 2704 gallons of treated antifreeze to release an equivalent mass of denatonium benzoate."<sup>2</sup>

<sup>&</sup>lt;sup>2</sup> Denatonium Benzoate Report, ME Dept. of Environmental Protection, February 13, 2006, p. 11.

MTBE was able to cause such damage to drinking water supplies in large part because gasoline is stored in underground tanks. About 9 million gallons of gasoline are released to the environment each year due to spills and leaks. At no time is either DB or antifreeze stored underground.

That same report by the Maine Department of Environmental Protection cited a conversation with Ken Kaufmann, Oregon's state toxicologist, in which he stated that "'no incidents of drinking water well contamination or groundwater contamination or bad tasting water due to denatonium benzoate have become known.""<sup>3</sup>

EPA data indicate that MTBE is a potential human carcinogen at high doses. At low doses, such as the low levels needed for aversion, DB exhibits low mammalian, avian, and aquatic toxicity. There is a record of only one negative reaction to DB, which occurred in 1978 in a hypersensitive man.

#### **Efficacy Issues**

Questions have been raised about whether the addition of DB to antifreeze will indeed prevent poisonings. Most of those expressing doubts about DB's efficacy point to a June 2004 retrospective review by Mullins and Horowitz of Oregon Poison Control Center (OPCC) records of pediatric exposures to antifreeze and windshield washer fluid for the period 1987-2003, as well as coroner reports of poisoning deaths between 1994-1997. <sup>4</sup> OPCC reported "no change in frequency" of pediatric poisoning frequency after 1995. The authors also found that "no child died or suffered 'major' effects before or after 1995." They concluded, "The mandatory addition of denatonium benzoate to automotive products has produced no measurable reduction in unintentional pediatric toxic alcohol exposures in Oregon."

Not only are there deficiencies in this report, but it must also be placed in the context of other reports that point to the efficacy of DB.

- The overwhelming problem with antifreeze poisonings, in terms of number and mortality, occurs among animals, chiefly household pets. The Mullins/Horowitz review does not even consider this aspect of the issue. Unfortunately, it would be difficult to perform a similar evaluation of animal poisonings as there are no reporting requirements, in Oregon or elsewhere.
- This evaluation actually argues in support of a uniform national standard inasmuch as it does not account for the effect of the use or misuse of antifreeze purchased outside Oregon.
- The Mullins/Horowitz retrospective survey does not take into account variable levels of DB in antifreeze and windshield washer fluid. A state study <sup>5</sup> done in 1996 found considerable variability in the amount of DB present in various consumer products. The availability of consumer products that are not in

<sup>&</sup>lt;sup>3</sup> Ibid., p. 8.

<sup>&</sup>lt;sup>4</sup> Mullins and Horowitz, Vet Hum Toxicol, 2004 Jun;46(3): 150-2.

<sup>&</sup>lt;sup>5</sup> The Oregon Health Division is responsible for monitoring compliance with the required addition of a bittering agent to consumer products under the Household Toxic Products Rules, but there is no protocol for periodic testing. Henderson et al. [Chemosphere. 1998 Jan;36(1):203-10) developed a sufficiently sensitive High Pressure Liquid Chromatography method for analyzing DB in consumer products. They analyzed antifreeze and windshield washer fluid products purchased in Oregon 1994 and 1996. The concentration of DB in the products purchased in 1994 ranged from non-detectable (less than 1.25 ppm) to 30.9 ppm, with 7 out of the 10 products having undetectable levels. In 1996, the concentration of DB in antifreeze ranged from 26.4 to 32.6, with no non-detects. The concentration of DB in windshield washer fluid ranged from non-detect to 30.1 ppm, with 8 of the 14 washer fluids having undetectable levels. Although this is a very small study, this indicates that in 1996, there was still considerable variability in the amount of DB present in various consumer products.

compliance with the law suggests not merely that the impact of the law (i.e., decrease in child and animal poisonings) may not be measurable for some time, but also that the purpose of the law is actually undermined. This situation argues in favor of a uniform federal standard for bittering antifreeze.

This is not the only indication that the Mullins/Horowitz survey may have been premature. A 2001 analysis of data by the staff of the California Integrated Waste Management Board (CIWMB) suggests that it would be ill-advised to make judgments about the efficacy of denatonium benzoate on the basis of experience over a relatively short time period by noting that "[c]omparatively, it took 17 years to conclusively prove that child-resistant caps were effective in reducing child exposures in general."

It is true that data on the efficacy of DB are not abundant, and that data exist on both sides of the question. That being said, however, there is evidence of its usefulness in preventing or mitigating ingestion of substances by children and animals.

For example, in its memo supporting *West Harlem Environmental Action v. U.S. EPA*, the Natural Resources Defense Council<sup>6</sup> wrote: "...EPA claims that it revoked the bittering agent requirement because of efficacy concerns, but EPA's own analysis disproves these concerns. Before requiring the safety measures, EPA reviewed scientific studies on denatonium benzoate, a possible additive and 'the bitterest substance known to man.' EPA 01131. A field study of a rodenticide containing 10 parts per million of this bittering agent resulted in a '95% reduction in rodent activity.' *Id.* The same level of bittering agent in different household products 'was found to reduce the amount ingested by children.' *Id.* This record evidence supports the conclusion that a bittering agent can effectively control rats and deter children's exposure."

In 1963, the FDA approved the addition of denatonium benzoate to cosmetic and toiletry products as a safety mechanism to deter children from ingesting these products. It is used in hundreds of products to render them unpalatable, including cleaning agents, other household products, cosmetics, and personal care products—everything from detergents and aftershave to fire extinguisher fluid, gasoline, pesticides and herbicides, ink, wax crayons, nail polish remover, bubble bath, hair spray, and eyeshadow. It is even in veterinary sprays and ointments. In 1989, the U.S. Department of Agriculture approved it for food plant use.

Also, according to the Center for the Science and Engineering of Materials<sup>7</sup>, DB "is recognized as the bitterest substance known. When it is added in only minute quantities to potentially harmful household, garden or automotive products, this harmless additive renders these products unpalatable and becomes a powerful deterrent against poisoning especially in young children."

Likewise, the CIWMB staff study also found "that the addition of denatonium benzoate may not prevent exposures, but it would significantly reduce the amount ingested, hence the severity of exposures. Numerous studies have shown that it does repel animals, though until it is used extensively in antifreeze, the magnitude of its effectiveness for animals in ethylene glycol based antifreeze will be difficult to verify."

One such study is "Denatonium benzoate as a deterrent to ingestion of toxic substances: toxicity and efficacy"<sup>8</sup>, in which the authors conclude the following:

<sup>&</sup>lt;sup>6</sup> West Harlem Environmental Action v. US EPA, Memorandum in Support of Plaintiffs' Motion for Summary Judgment, filed by the Natural Resources Defense Council in US District Court for the Southern District of NY, March 29, 2005; pp15-16

<sup>&</sup>lt;sup>7</sup> "The National Science Foundation sponsors a network of Materials Research Science and Engineering Centers (MRSECs) at U.S. universities. The Center for the Science & Engineering of Materials (CSEM) at Caltech is one of them. The goal of the program is to stimulate interdisciplinary research and education in materials." (CSEM Fact Sheet)

<sup>&</sup>lt;sup>8</sup> Hansen SR, Janssen C, Beasley VR. Vet. Hum. Toxicol. 1993 Jun; 35(3):234-6.

"Since there is evidence that some taste aversion agents reduce the quantities of liquid substances ingested by dogs, and there is evidence that denatonium benzoate reduces ingestion quantities by children, denatonium benzoate may reduce the seriousness of accidental exposures to harmful fatal substances in dogs. This deterrent potential in animals needs to be investigated further. Denatonium benzoate should be added to toxic substances available in and around homes which, when ingested, represent serious hazards to animals and children."

Given that there is evidence of an aversive reaction to DB by animals; that there is no evidence indicating animals or children might be harmed by this safety measure; and that animals are likely to benefit from this step and children almost certainly will benefit—coupled with the long history of DB's use (and recognized value) as a bittering agent—a strong case can be made in favor of a policy decision to require the addition of a bittering agent to this indisputably toxic substance even in the face of some scientific uncertainty. We feel that this is a wise step to take since the possibility exists for preventing some poisonings or at least mitigating the severity of those that do occur.

#### **Environmental Issues**

As an animal protection organization, we would not advocate the use of chemicals that would harm the environment, animals, or human health, so we do not take lightly the environmental concerns that have been raised about DB. We have based our support for adding denatonium benzoate to ethylene glycol antifreeze not only on the prospect of preventing poisonings, but also on an extensive record of safe use both here and abroad.

DB is a chemical that has been used safely and effectively as an aversive agent in this country for over 40 years; as noted earlier, in 1963 the FDA approved its use in cosmetics and toiletries to deter children from ingesting them. It is used in dozens of other household and personal care items, cleaning agents, and many other products, such as deer repellent, that make their way into the municipal waste stream or are deposited directly on or applied to the environment. Bitrex, one of the commercial brands of DB, "has been officially recognized as the denaturant of choice in more than 40 countries."

While some data gaps exist for hazard identification, state and federal regulators ultimately assess for *risk*. With that in mind, it should be noted that:

- The CIWMB staff analysis found that DB "readily biodegrades, its transport is attenuated by soil, and it is easily treated in sewage treatment systems and drinking water systems. Staff has determined that the addition of [DB] to antifreeze would not lead to any adverse health or environmental effects."
- > DB exhibits low mammalian, avian, and aquatic toxicity, especially at the levels used for aversion.
- Ethylene glycol antifreeze is already rigorously managed as a hazardous substance; waste antifreeze may contain lead, cadmium, and other heavy metals. According to EPA, dumping antifreeze can cause serious water quality problems. Therefore, the industry urges consumers and large-scale users to dispose of used antifreeze properly. That will not change when DB is added in the minute quantities needed as a bittering agent. The Consumer Product Safety Commission's testimony at the Senate hearing confirmed that DB will contribute little or no incremental hazard or risk to human health when added to ethylene glycol antifreeze.

# Conclusion

Antifreeze poisoning causes animals great suffering and often death. In addition to the accidents that happen, DDAL knows of numerous cases where individuals have deliberately given antifreeze to animals because they wanted to kill them. Our very informal tally of cases of both deliberate and accidental poisonings includes eight alleged antifreeze deaths in Iowa, and others in Florida, Maine, Michigan, Missouri, Montana, Mississippi, Pennsylvania, Tennessee, Texas, and elsewhere. We worked with a family in Georgia who sought justice for their two dogs killed by a belligerent neighbor. State Representative Kathy McCoy, who successfully carried the bill in New Mexico, lost her own companion animal in the same way. Suicides and murders involving antifreeze have occurred in Florida, Georgia, Kansas, Maryland, Massachusetts, Missouri, New Jersey, and Pennsylvania.

Where the perpetrator in a deliberate poisoning case is known, it often is a neighbor; occasionally, it is an adolescent just starting down the path of antisocial behavior. They use antifreeze because it is easy to get, easy to give, and almost guaranteed to kill.

Because of its widespread acceptance, and because consumer demand for less toxic alternatives has been slow to develop, we fully expect ethylene glycol-based antifreeze to continue to dominate the market for the foreseeable future. Therefore, accidents will continue to happen despite the best prevention and precautions, and sadly there are always those who seek an easy way to harm animals. These are needless tragedies that touch many lives. This legislation will do much to prevent both kinds of tragedies from happening.

Please support moving H.R. 2567, the *Antifreeze Bittering Act*, to the floor for consideration by the full House of Representatives.

MR. GILLMOR. Thank you very much. With regard to the letter that you wanted entered into the record, without objection, hearing none, it will be entered in the record.

[The information follows:]

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**Executive** Office Tam M. Daduc, Board Chair 1001 1 Street • Szcramento, California 95814 • (916) 341-5615 Mailing Address P.O. Box 100 • Sacramento, California • 95812-0100 Fax (916) 341-5621 • http://www.waterboards.ca.gov

May 15, 2006

Ms. Sara Amundson Deputy and Legislative Director Doris Day Animal League 227 Massachusetts Avenue, NE, Suite 100 Washington, D.C. 20002-4963

Dear Ms. Amundson:

# ADVERSE EFFECTS OF DENATONIUM BENZOATE ON WATER QUALITY

I am writing in response to your inquiry regarding California's experience to date with requiring the addition of the bittering agent denatonium benzoate to ethylene glycol-based antifreeze (Business and Professions Code Section 17582). Specifically, you asked whether there have been any adverse effects on water quality arising from the use of this additive since the law went into effect in 2002.

Even though it is regarded as the bitterest known substance, to date we are unaware of adverse impacts to California's water supplies arising from the use of denatonium benzoate in antifreeze and a variety of other products.

Please contact me at the above-referenced phone number, or by email at ccantu@waterboards.ca.gov should you have any further questions.

Sincerely,

beth man

Celeste Cantú Executive Director

California Environmental Protection Agency

Recycle Paper

HUMAN POISONING CASES (Based on news reports.)

**Apr. 2006, Milwaukee, WI:** The state Supreme Court will rule on the admissibility of evidence in the trial of a man accused of murdering his wife, who died from a lethal dose of ethylene glycol. (*Duluth News Tribune*, April 16, 2006; *Washington Post*, April 17, 2006; *The Electric New Paper*, April 19, 2006)

Feb. 9, 2006, Anne Arundel Co., MD: Firing of police officer upheld for failing to obtain medical care for prisoner who later died from having ingested antifreeze (had already ingested it at the time of his arrest for drunk driving).

Feb. 2, 2006, Tallahassee, FL: Story about bribery case against former FL Senate president and Escambia Co. commissioner noted that a fellow county commissioner who had testified against him committed suicide by drinking antifreeze. (*Bradenton Herald*, February 2, 2006)

Jan. 27, 2006, Pittsburgh, PA: Terry Long, a former player for the Pittsburgh Steelers, committed suicide by drinking antifreeze, and did not die as a direct result of football-related head injuries as first reported. (*The New York Times*, January 27, 2006)

Jan. 11, 2006, Marietta, GA: Judge denied request for new trial for woman convicted of killing her policeman husband with antifreeze in 1995. She is scheduled to be tried later in the 2001 antifreeze poisoning death of her firefighter boyfriend. (*The Ledger-Enquirer*, November 14, 2005)

Nov. 16, 2005, Orlando, FL: A Lake Mary area woman faces a charge of attempted murder after authorities accused her of giving her husband a glass of antifreeze, Seminole County deputy sheriffs said today. (*Orlando Sentinel*, November 16, 2005)

**Nov. 10, 2005, Cambridge, MA**: MO talk show host arraigned in MA court accused of killing wife in 2004 (when they lived in MA) by spiking her Gatorade with antifreeze over a period of time. (WCTB TV on December 7, 2005 and *Boston Globe* on November 10, 2005)

**Nov. 3, 2005, Kansas City, KS:** A couple accused last year of trying to kill the mayor of Edwardsville and her family with tainted cupcakes and root beer laced with antifreeze were sentenced Thursday to probation. (KMBC TV, November 3, 2005)

Oct. 21, 2005, Belton, MO: Police arrest woman in CA for 1993 antifreeze poisoning death of her husband. (*Democrat Missourian*, October 21, 2005)

July 2004, Shamong Twp., NJ: Woman charged with killing her brother-in-law by spiking his fruit drink with antifreeze. (cnn.com, July 12, 2004)

**Other Human Poisonings:** Ingestions of antifreeze by children (between the ages of 6 and 19) in 2003: 1395 (no deaths reported) Intentional ingestions (suicides) in 2002: 21

ANIMAL POISONING CASES (Intentional and Accidental; compiled from news reports. Annual estimate is 10,000 animals are poisoned by antifreeze.)

May 12, 2006, Pflugerville, TX: One family's 3 dogs deliberately poisoned with antifreeze by unknown person. (KVUE.com, Austin, TX, May 12, 2006)

May 6, 2006, Knox, TX: In a story about new cases of intentional poisonings of dogs, it was reported that antifreeze killed two other dogs in March. (*Times Record News*, May 6, 2006)

May 5, 2006, Bartlett, TN: On March 31, Mickey, a sheltie belonging to the Thompson family, died of antifreeze poisoning. (*Bartlett Express*, May 5, 2006, and WMC-TV, April 28, 2006))

May 2, 2006, Tampa Bay, FL: Man in Lutz, FL, charged for the second time with animal cruelty; police reported that "a bowl was found in [his] back yard full of a deadly mixture of dog food and antifreeze." (WTSP, Tampa Bay, May 2, 2006)

Apr. 29, 2006, Livingston Co., NY: "Investigators in Livingston County are working to find the person or persons intentionally poisoning dogs with antifreeze..." A Cornell University toxicologist "found chunks of meat that were not digested and that were laced with a large dose of antifreeze." (WHAM Ch. 13, Rochester, NY, Apr. 29, 2006)

**Apr. 22, 2006, Britt, MN**: Report of lack of progress in finding person(s) responsible for causing the deaths of 3 dogs last fall by lacing hot dogs with antifreeze. Both families had also had dogs poisoned 5 years ago. (*Mesabi Daily News*, Apr. 22, 2006)

Apr. 22, 2006, Lutz, FL: A 16-year-old dog died after eating from a bowl in a neighbor's yard. A bowl matching the description was found to contain dog food mixed with engine coolant. (Pet-abuse.com)

April 2006, Stockton Springs, ME: A family had to euthanize its dog and cat after they were both poisoned with antifreeze by an unknown person. (*Bangor Daily News*, April 22, 2006, with subsequent confirmation from the ACO that antifreeze was used.)

**Apr. 3, 2006, Anderson Co., TN:** Several animals in one neighborhood have died, apparently as a result of antifreeze poisoning. Tests confirmed antifreeze poisoning as the cause of death for 3 cats; other pets who died exhibited signs of having ingested antifreeze. (WBIR, Apr. 3, 2006)

Mar. 30, 2006: Abbott, ME: Local authorities are investigating the suspicious deaths of two dogs, who may have ingested antifreeze-tainted meat. Two other dogs survived. (*Bangor Daily News*, March 30, 2006)

Mar. 10, 2006, Tennessee: Story on coping with loss of a pet included story of woman who had to euthanize her beloved dog after he accidentally ingested antifreeze. (*The Tennessean*, Mar. 10, 2006)

**Feb. 10, 2006, U.S. Virgin Islands:** At least five pets - two dogs and three cats - have died in the last two weeks from antifreeze poisoning, according to veterinarians. While noting that antifreeze poisoning is a common accident, one of the vets said this many deaths in such a short period could be "malicious." The owner of one of the dogs said that several dogs in his neighborhood had died recently.

Jan. 12, 2006, PA: The Calisiti family's two dogs, Duke, a 7-year-old beagle-Lab mix, and Bailey, a 3-year-old yellow Lab, had to be euthanized after ingesting antifreeze. It is not yet known whether these were deliberate or accidental poisonings. (*Pittsburgh Daily Courier*, January 17, 2006)

Jan 11, 2006, Sudbury, VT: According to police, the dog's owner let the two dogs, a collie and a corgi, out on their property on the morning of Jan. 11, 2006; when the dogs returned, they were severely vomiting. The dogs were rushed to the vet, who diagnosed antifreeze poisoning. Both dogs were euthanized the following day as a result of the poisoning. Authorities to believe the dogs may have been intentionally poisoned.

January 2006, LA: Discovery of 13 cats in New Orleans who had died of antifreeze poisoning. (www.animalrescueneworleans.com)

December 2005, GA: Death of 10 year-year old chow-mix, Buster.

**Dec. 3, 2005, Tyler, TX**: The Morgan family's dog, a chow-retriever mix, and the Smith family's two dogs, a bull mastiff and a Jack Russell terrier, all died after ingesting antifreeze. The cases are being treated as intentional poisonings. (*Tyler Courier-Times Telegraph*, December 3, 2005)

**Dec. 1, 2005, Avoca, IA**: Police K-9 drug dog was poisoned with antifreeze. Dog recovered. (*Harlan Tribune*, December 1, 2005)

Nov. 29, 2005, Cornelius, NC: Woman charged with cruelty and disorderly conduct for poisoning neighbor's cat with antifreeze; cat expected to recover. (WSOC TV, November 29, 2005)

**Nov. 10, 2005, Spanaway, WA**: Judge rejects plea deal in case of woman charged with poisoning neighbor's 3 cats with antifreeze, determining that she should go to trial on the 3 felony charges. (Pasadosafehaven.org)

Nov. 3, 2005, Bellevue, NE: A couple's 2 huskies died after eating antifreeze-tainted meat. (*Omaha World Herald*, November 3, 2005)

**Oct. 26, 2005, Belle Vernon, PA**: Police investigating 2 recent dog poisonings, one definitely attributable to antifreeze, the other undetermined as of yet. (*The Valley Independent*, October 26, 2005)

Oct. 20, 2005, Palm Bay, FL: Ducks poisoned by antifreeze left open on a patio. (Florida Today, October 20, 2005)

Aug. 28, 20005, Bryan-College Station, TX: 12 dogs within 5 blocks of one another die after ingesting antifreeze. (Bryan-College Station Eagle, August 28, 2005)

Aug. 17, 2005, Ketchikan, AK: Couple writes of the death of their black lab from ingesting antifreeze that had been spilled on a boat ramp. (*Sitnews*, August 17, 2005)

July 31, 2005, Hickory, NC: Dog dies after ingesting antifreeze. (Not able to ascertain whether intentional or accidental poisoning.) (*Hickory Daily Record*, July 31, 2005)

July 19, 2005, Elgin, AZ: 2 of 3 family dogs die from antifreeze poisoning; 3<sup>rd</sup> dog disappears. (www.nogalesinternational.com, July 19, 2005)

Jul. 18, 2005, Mt. Oliver, PA: Antifreeze suspected in deaths of 3 dogs on the same block. (WTAE TV Channel 4, July 18, 2005)

Apr. 12, 2005, Knoxville, TN: Man charged with poisoning cats with antifreeze.

April 2005, Rankin, MS: 2 dogs (and possibly 3 as one is barely alive at time of report) die as a result of antifreeze poisoning. (WLBT TV, April 21, 2005)

Feb. 17, 2005, Jacksonville, FL: Man admits to killing neighbor's dog with antifreeze. (WTEV TV, February 17, 2005)

Jan. 2, 2005 Orlando, FL: 2 dogs in same neighborhood die after eating antifreeze-laced food. (WFTV TV, January 4, 2005)

MR. GILLMOR. Let me start with Mr. Simms. A couple of questions. You talked about the necessity of balancing risk, and it was unfair that the public bear the whole risk. If we look at this situation, we know on one side there is a risk of death to children, and, if Mr. Ackerman's testimony is correct, 1,400 children a year, that means on average we have more than 100 children every month dying from the lack of a bitterant in antifreeze. On the other hand, we weigh the chemical DB, which so far we have no evidence of a risk, and we know it is used in hundreds of products, and in this case it would be a very minimal use, only 7,000 gallons. Would you explain to me how it is a good value judgment on our part to let 100 children die a month, instead of taking a small amount of this agent, which has no risk shown, and trying to save those children?

MR. SIMMS. I will answer your question, but I want to make a couple of clarifying points. One, our objection is to the liability waiver. Removing the liability waiver does not--

MR. GILLMOR. If the liability waiver were not in here, would you support the bill, saying we ought to mandate the addition of DB, period?

MR. SIMMS. What we object to is the liability waiver and the preemption of State authority to regulate.

MR. GILLMOR. Well, you still haven't answered my question.

MR. SIMMS. Okay, I will answer. If those two points in the bill were absent, we would not be objecting to the bill.

MR. GILLMOR. And not be objecting?

MR. SIMMS. That is correct.

MR. GILLMOR. Is that the same as supporting or is that the same as waffling?

MR. SIMMS. I will give you the best answer that I can give. The only reason that we are objecting to the bill is the liability waiver and the preemption. Assuming that those two things were gone, we would look at the bill again and determine whether it was worthy of support. Given the balances that you have just discussed, my assumption is that we would support it. And in fact, we are strongly in support of bills such as this that have, as their objective, the protection of public health and the environment, and in fact, have recognized bitterants as a way of achieving that for poisons that otherwise are--

MR. GILLMOR. Let me ask you, in terms of preemption, would you agree that there are certain cases in a national market where a product made in one State is shipped to all 50 States, as Mr. Ackerman pointed out, a car drives all the way across the country with that product, isn't there a reason, which we do in a lot of cases, for having a uniform standard? What is the holy grail of not having a national standard when you are talking about a chemical like DB and you are talking about a product that is used all over the country. The antifreeze that I get in Ohio isn't any different than the antifreeze in Florida or Kentucky. Why shouldn't there be a national standard?

MR. SIMMS. I am not suggesting that there should not be a national standard.

MR. GILLMOR. Well, that is what preemption is.

MR. SIMMS. But let me clarify. I mean, what we are suggesting is that if Congress decides to adopt a national standard and that standard says, use a bitterant and use it, sufficient to be adversive for this highly toxic material, then States should be able to regulate beyond that to the extent that they believe it is necessary to protect their citizens, but it wouldn't preclude that national standard from being in place.

MR. GILLMOR. But it wouldn't be a national standard. It could be a national standard--

MR. SIMMS. It would not be a uniform national standard.

MR. GILLMOR. --with 50 different amendments.

MR. SIMMS. It is not clear to me why there is any expectation that that would happen and why, therefore, there is a need to preempt that in the bill.

MR. GILLMOR. Well, it is already happening. You have three States adopting a different standard, and you have 10 others considering it, so I mean that is the concern. Let me ask you just one more thing, regarding your concern with DB. On March 29 of last year, your organization submitted a motion for summary judgment in West Harlem Environmental Action v. U.S. EPA. In that case, you argued that the EPA should require a bittering agent, including DB, in rat poisoning, to protect against unhealthy ingestion by children and deer, and you stated the evidence from DB tests supports a conclusion that a bittering agent can effectively control rats and deter children's exposure. So I mean, why do you think Governor Richardson, who sent us a letter in support of the bill and a letter against the bill--

MR. SIMMS. Respectfully, I disagree. We are not suggesting that bittering agents cannot be effective ways to prevent unwanted ingestion of harmful chemicals. Far from that; we have recognized them as a valuable means of doing that. Some context to that particular case: what we were challenging was EPA's withdrawal of the protection of bitterant and marking dyes in rat poison, which it had decided to impose, based on a specific finding that rat poison posed an unacceptable risk to health, poisoning in the range of 15,000 to 50,000 children a year, and we argued that they could not remove that protection without imposing some alternative protection for human health and accidental poisonings. And in doing so, we argued that they needed to reimpose that requirement, that we acknowledge would protect people from unwanted poisonings. But by no means is our position here inconsistent. We do not argue here that bitterants are ineffective or we know nothing about their use in antifreeze. We have not looked at that or studied that. We certainly would say that they are effective in some context and very useful in some context. The problem here is with letting industry off the hook for any liability that might occur down the road, in an instance where some harm does occur.

MR. GILLMOR. We could pursue it further, but my time has expired, so let me go to Ms. Solis.

MS. SOLIS. Thank you. My question is for Dr. Eyrich. Did I pronounce that correctly? I wanted to ask you if you would support mandating the use of another antifreeze formulation called propylene glycol, which would be significantly less toxic and meets the testing standards for an engine coolant and corrosion properties?

DR. EYRICH. Thank you for your question. I am aware of propylene glycol. From a medical standpoint, propylene glycol will also respond to the test they use to test for ethylene glycol, and so it makes it very difficult, in a medical situation, to actually understand what the animal has actually been exposed to. Antifreeze or ethylene glycol is still a very common chemical, and I think there are people in this room that are more qualified to answer the question of whether it is no longer going to be used any time in the immediate future or be replaced entirely by propylene glycol. And certainly, alternatives should be looked at or entertained as much as possible.

MS. SOLIS. Thank you. And I think that is what some of us are trying to get at, if there is a way to look at other types of additives that are not going to be as harmful to the public health and to, obviously, our water, in this case, and to habitat. And I just wanted to clarify, also, from Mrs. Amundson. You talked about legislation in California that was passed. Certainly, they have been ahead of us on many things, and in this area they did provide for a liability waiver for manufacturers and what have you, but they did not waive liability for environmental damage or natural resources, much like the State of Oregon. So let us be clear on that what we are looking at here, in terms of this legislation, is sweeping. This will actually remove that liability through the whole process and that is something that just doesn't sit well with some of the members of this committee, and myself included. I am concerned about that.

And I also wanted to go to Mr. Bye, regarding your testimony. You said, on page six, the proposed Federal legislation would not change the liability of antifreeze manufacturers for the products. Under the legislation, antifreeze manufacturers continue to be liable for ethylene glycol antifreeze itself, and DB manufacturers and distributors are liable. I mean, from what we are hearing here, it sounds like we have some very, very different perceptions of who is going to be held liable and who is not. Can you explain your statement again?

MR. BYE. Yes. Our position is very clear on this. As I said, we are experts on what our product does in the cooling system of a car. That is where our chemists work, and that is what our expertise lies in. We are not experts in any way, shape or form, and so we fully stand behind, always have and always will, any issues that are our product: the antifreeze and the components of it that are designed to work in a car's cooling system, any impact they have on the environment. On any liability situation, we are fully supportive of, always have been and always will be. When we are asked to put a component into our product that we are not experts in--

MS. SOLIS. Yes.

MR. BYE. --that is where we feel we should not be held liable for any impact that product may have, but we feel that full liability should resort to and be assigned to the people that manufacture it and supply it. So that is just where the distinction comes, just where our area of expertise lies, and that is not with a bittering agent; it is with car cooling systems.

MS. SOLIS. Yes. And if I ask you the same question, would you support mandating the use of another type of additive that I mentioned, propylene glycol, which is less toxic.

MR. BYE. Yes, we are the leading seller today of propylene glycol product in the United States.

MS. SOLIS. Yes.

MR. BYE. Order of magnitude, we sell 250,000 gallons, plus or minus, out of a total of 50 million. It is readily available at Wal-Mart, AutoZone, anywhere else. It has some issues with it that would cause us probably not to be supportive of it, but not the least of which is, it is only slightly less toxic to start with. Some could maybe address that better. But the biggest issue for us, on the automotive side, is that it has different cooling capabilities. It requires different additive packages for corrosion, and the net of all that is, it would require the car manufacturers to redesign engine cooling systems.

MS. SOLIS. My time is almost up, so I want to, if I could--sorry to interrupt.

MR. BYE. Yes.

MS. SOLIS. But wasn't it true that in the 108<sup>th</sup> Congress, Honeywell and the trade association, Consumer Specialty Products, opposed H.R. 1563, which required DB to be added in the antifreeze?

MR. BYE. We didn't oppose generally, we have opposed it on a State basis, prior to late 2004, for many of the reasons stated.

MS. SOLIS. You did not oppose that Federal piece of legislation that was introduced in the 108<sup>th</sup>?

MR. BYE. I do not believe so. Oh, we did? Okay. I just had the bill numbers mixed up.

MS. SOLIS. My understanding is that--

MR. BYE. You were correct. I had the bills--

MS. SOLIS. -- the information that was provided back--

MR. BYE. Right.

MS. SOLIS. -- at that time was submitted by your association--

MR. BYE. No, you are correct.

MS. SOLIS. --in opposition.

MR. BYE. Yes.

MS. SOLIS. In opposition.

MR. BYE. Yes.

MS. SOLIS. That is a lot of information, by the way.

MR. BYE. Yes.

MS. SOLIS. An analysis that has been done that I believe EPA mentioned that they did not have a chance to look at, testing that had been done by your trade organization.

MR. BYE. We provided all of that information to everybody on the panel, and we have always been forthcoming with all of that information.

MS. SOLIS. But with EPA, do you know if they have actually had an opportunity to--

MR. BYE. We did not provide it to them. We provided it to the panel.

MS. SOLIS. Okay. Mr. Bye, is it correct that there are a number of scientific studies, on the environment fate of DB, that shows it does not biodegrade in the environment and could present a risk to our groundwater?

MR. BYE. There may be. There are a number of conflicting studies. I am not familiar with the content of all of them. Again, that goes back to--

Ms. SOLIS. So these studies are included here in the--

MR. BYE. Yes, they are.

MS. SOLIS. --association that you represent.

MR. BYE. And as we have pointed out, there is conflicting data in there and hence our reluctance to take on full responsibility for the product.

MS. SOLIS. Can I go over?

MR. GILLMOR. I was going to let you go over, as much as I went over, but I think you are there.

MS. SOLIS. All right, thank you.

MR. GILLMOR. The gentlelady from New Mexico.

MRS. WILSON. Thank you, Mr. Chairman. Mr. Bonacquisti, I have a couple of questions for you. You said in your testimony that you don't

like the liability provisions, the separated liability allowing the DB manufacturers to be liable for their product and the antifreeze manufacturers to be liable for this product that is in this bill, and you called it unwise, unsound and unfair. In the spring of 2003, the American Water Works Association issued a press release stating that you supported an act called the Drinking Water Standards Preservation Act that would protect water utilities from lawsuits as long they are in compliance with Federal and State regulations.

MR. BONACQUISTI. Yes, that is true.

MRS. WILSON. Why is fair or sound and wise for you and unwise, unsound and unfair for the guy at the other end of the table?

MR. BONACQUISTI. Well, I think the water utilities are public health and public service entities. Our mission is to remove contaminants from a water supply, not to put them in, and if we meet Federal standards for drinking water contaminants, or if we are below those standards that have been set by a regulatory process, through EPA and the regulatory process, we should not be held liable.

MRS. WILSON. So if Mr. Bye complies with the Federal standards, he should still be liable, but if you do, you shouldn't because you are a nonprofit?

MR. BONACQUISTI. Well, if Mr. Bye's product went through a regulatory process.

MRS. WILSON. So your issue here is not that it is the difference between law and regulation. Is that what I am hearing here?

MR. BONACQUISTI. Well--

MRS. WILSON. I won't push you any further, but as I like to say at my house, only my mother can have it both ways, and I think you see my point here.

MR. BONACQUISTI. I understand.

MRS. WILSON. I wanted to ask a question of the folks from the NRDC, if I could, Mr. Simms. You talked about unacceptable risks and you talked about rat poison in particular, and the adding of bitterant to rat poisoning, that there is a level of unacceptable risk and that somewhere between 15--and as I think I hear you right, 15 and 50,000 children are poisoned per year with rat poison. At what point does the risk become unacceptable?

MR. SIMMS. Well, let me clarify. That was EPA's finding of unacceptable risk. And it was pursuant to fifth row, which is the--

MRS. WILSON. I am familiar with law.

MR. SIMMS. Yes. And so that was not our determination of unacceptable risk. It was a litigation that revolved around EPA's regulatory determination of unacceptable risk, and then active afterwards

with respect to rat poison that was inconsistent with that finding of unacceptable risk.

MRS. WILSON. Do you think that that is unacceptable risk for 15,000 children to be poisoned?

MR. SIMMS. Do I personally think that?

MRS. WILSON. Well, NRDC advocated for keeping the bitterant in the rat poison.

MR. SIMMS. That is right, that is right.

MRS. WILSON. So you agree that that was--

MR. SIMMS. We would leave it as it is. That is something that should be addressed.

MRS. WILSON. What the level of risk is.

MR. SIMMS. The level of risk, that level of risk from exposure to rat poison. Absolutely.

MRS. WILSON. The reason I wanted to hear what you had to say about that a little more is because that is what we are doing here, we are balancing risks. We have a known risk with antifreeze of about 1,400 children being poisoned each year, not dying but being poisoned, and about 90,000 animals per year, and we also have a low risk of an additive that is very common. And it seems to me that the trial lawyers are upset because they are going to have one less party to sue. Well, that is a risk I am willing to take, when the balance is on the other side of the number of people being poisoned.

Mr. Bonacquisti, one final question for you in the time that I have available. You talked about in your testimony, you said that it is inevitable that DB will eventually show up in the water system. There are other products that contain DB. We have gone through the list here, the shampoo, the things to clean my shower, all kinds of cosmetics and so forth. Have any of your members detected this as a problem now, and what do you and your association members use to get DB out of the water now?

MR. BONACQUISTI. Right now, I am not sure if we have detected DB. We would use some analytical techniques to do so. To get DB out of the water, I really don't know. We have different water treatment techniques to use for different types of contamination, but I don't think that there is a enough research or scientific data that has been accumulated so far to help our water utilities determine what the best avenue of treatment is.

MRS. WILSON. Well, you said in your testimony that somewhere, and perhaps in many places, contamination of drinking water supplies is likely to occur. We have been using this for 45 years.

MR. BONACQUISTI. Yes. And that is where we are going to have do our research.

MRS. WILSON. Where has it occurred?

MR. BONACQUISTI. We are going to have do our research to find that out. I mean, if DB is being added to larger and larger quantities of this antifreeze, then we will potentially see this in the drinking water supply.

MRS. WILSON. I mean, we are using it in hundreds of products already that are going down the drain and into the waste water, not into an antifreeze changing pool at Just Brakes or at Jiffy Lube. Have you had any cases where it has been detected in the water, and what is the treatment mechanism used--

MR. BONACQUISTI. Not to my knowledge have we had any detection on DB.

MRS. WILSON. So this statement that contamination of drinking water supplies is likely to occur, what is that based on?

MR. BONACQUISTI. On an increased volume of DB being added into antifreeze, if it is added.

MRS. WILSON. Thank you, Mr. Chairman.

MR. GILLMOR. The gentleman from Washington.

MR. INSLEE. Thank you, thank you. Mr. Bye, if this bill passed without the liability protection for you, would you quit making antifreeze?

MR. BYE. Would we quit making antifreeze?

MR. INSLEE. Yes.

MR. BYE. No, we would not.

MR. INSLEE. So the issue is whether or not citizens--they are going to get their antifreeze. The question is whether they are going to have--in the existing bill, they won't have relief if they get poisoned, and if we pass the bill without it, they will have the antifreeze and the protection of the judicial system in case they do get poisoned, right? Is that pretty much the deal?

MR. BYE. If the bill passes?

MR. INSLEE. If the bill passes without the liability waiver for the manufacturer of the antifreeze, consumers will get the antifreeze, you are going to keep making it--

MR. BYE. Yes.

MR. INSLEE. --to keep their cars running, and they will also have existing protection in the judicial system in case they get poisoned, against the manufacturer of the antifreeze, right?

MR. BYE. Correct.

MR. INSLEE. Okay. So if we pass this bill without the liability provisions, we will get the antifreeze, the cars will still work, the dogs won't get poisoned, the kids won't get poisoned, and in case somebody

gets poisoned by the product, Americans will have what they have today, which is the right to a judicial remedy, is that the deal?

MR. BYE. They certainly will.

MR. INSLEE. Okay. That is why I think it probably makes sense to take the liability provision of this thing out of here, because there is no reason for it. I want to ask Mr. Bye or anyone else this: why mandate a specific chemical? If we want to solve this problem, why don't we just mandate a bittering agent that meets a certain characteristic? Why wouldn't that be a preferable way to do this? Can anybody articulate that? Anyone?

MS. AMUNDSON. If I may, Congressman. I guess now is the time to step up a bit. Mr. Bye could certainly address why it is that denatonium benzoate is the chemical of choice in this situation, but I do want to say that we have had the opportunity to experience markup on this bill on the Senate side, and this is an issue that did arise at that time and the sponsors did address it through an amendment. I have no idea, and obviously I cannot speak for the sponsors for this bill, but there is the possibility that an equivalent chemical that demonstrates the things that we are asking DB to demonstrate in the Senate version of the bill, could be a way of addressing this issue.

MR. INSLEE. I am sorry. You know more about that different universe, the Senate, than I do. But what was the amendment? There was an amendment to allow alternatives, then?

MS. AMUNDSON. There was an amendment to, in essence, create a study provision on denatonium benzoate and also to allow for the addition of other additives that demonstrated what DB did under the auspices of that study and performed an equivalent level of protection without injuring cars' engines.

MR. BYE. And to that point, if you asked for all of our comments, we as an industry, I can't speak to the effectiveness of one over the other. That is somebody else's expertise, how it works in dogs and all. I can tell you that DB was analyzed by us for its impact on a car's cooling system. So any other substance that came along would have to go through that same process on our side, and the bill refers to that point. It also has to be compatible with the car's cooling system, and that would be our only point of view.

MR. INSLEE. You mean the Senate bill, the Senate amendment?

MR. BYE. Yes.

MR. INSLEE. I see. Coming back to--yes, Mr. Simms.

MR. SIMMS. If I could add to that, I think that is a very good question. And one of our primary concerns is, why would we close the door to competition in the future, remove the flexibility that would allow industry to address needs in the future, if some other problem arises with

this bitterant, or if some other bitterant proves to be more effective, more available, more economical.

MR. INSLEE. Right.

MR. SIMMS. I just wanted to reinforce that.

MR. INSLEE. Got you. Coming back to this liability issue, I think that the rationale, if there is one, for the liability protection is, if Congress mandates it, that manufacturers shouldn't be liable for putting it in, I can understand that a little bit. But it seems to me, doesn't it make sense that if you do remove protection of Americans who now have protection, if they get hurt by a product, they have got the right to reimbursement for their damages, and if we pass it, we would be stripping Americans of that right. If we were to do that, shouldn't the Federal government replace it with some compensation plan through the Federal government?

MR. BYE. Well, my understanding is, we are not stripping them of the right to do that. We are assigning the person that they would go after for their damages.

MR. INSLEE. Well, that is in heaven where all defendants are solvent with huge insurance. And I can assure you, looking at the Exxon situation, where they took a billion dollars out of my constituents and now they have \$2 in the till, that is not the way the real world works. You are stripping Americans of having a right to compensation from a solvent defendant. And in many cases, particularly this case, where you can have significant damages, frankly, including the MTBE situation, the manufacturer of the sub-particle component is going to be gone, toast, history, nothing, and you are going to effectively eliminate any right to a nickel for the people who could potentially be damaged by this product. Now, despite the fact that my friend from New Mexico's comment that just the trial lawyers are the only one with the stake, a game, you know-as a former practicing lawyer. I can tell you that they are the truck drivers, they're teachers, they are pharmacists, who can get hurt. And it is not the trial lawyers we ought to be thinking about, it is the people who can get poisoned by this product, and they today have a right to compensation that Congress would be taking away from them in the real world if we pass this with that liability provision. What I am suggesting is, if we do that, shouldn't we substitute a Federal compensation package for them in lieu of that? Would that make sense, if we were going to remove this liability, this claim? Anybody have any thoughts about that?

MR. GILLMOR. Well, the gentleman's time has expired.

MR. INSLEE. Thank you.

MR. GILLMOR. The gentleman from Oklahoma.

MR. SULLIVAN. Thank you, Mr. Chairman. And my first question is to Mr. Simms. Your testimony makes a reasonable suggestion that

antifreeze manufacturers have a choice in the adversive agent that they use in their product. However, to put your legislative recommendation into context, you would be requiring companies to reformulate a wellknown, 70-year-old product, but not give these same companies any support for doing these new activities. Since you are unwilling to support providing targeted legal cover for compliance with this additional mandate to longstanding manufacturing practices, is your concern based more on the impact of the adversive on the environment, or simply the ability to sue the antifreeze manufacturer if there is a problem with the adversive?

MR. SIMMS. I think that the point is more complicated or multifold. There is the question, when something goes wrong, if something goes wrong, someone is injured, does that person have the legal remedies available to them that are appropriate? It is about preserving the rights of people who are injured to be made whole by that industry that is benefiting from having the product in the marketplace. And the fiction that the DB manufacturer should be responsible for the DB, ignores the fact that the DB is in the antifreeze because the antifreeze is unsafe. And if the antifreeze producers, in that chain, that they should be in part responsible for injuries that might occur from that chemical that is there to make their product more safe. And that is not suggesting that the DB manufacturer should be let off the hook. They should bear their share of the responsibility, and the public, as I have said, always bears their share of the responsibility, because ultimately they are the ones who end up getting injured if something goes wrong. If nothing goes wrong, then the removal of the liability waiver is of negligible consequence to the industry. It is the question of who are we protecting.

MR. SULLIVAN. Thank you. And Ms.--I know Edmonsons from Oklahoma, so Amundson. Is that how you say it?

MS. AMUNDSON. Amundson. Thank you.

MR. SULLIVAN. Amundson, okay. Well, since the California law was passed in 2002, has there been any reduction in poisoning deaths, accidentally or otherwise? If not, why is that? And spills on highways aren't likely to be a source of antifreeze ingestion for children or household pets, or are they?

MS. AMUNDSON. The latter question first. Spills on highways, no, not necessarily, but it is driveways and it is the way that antifreeze is stored in containers inside of those garages that we are particularly concerned about. For obvious reasons there are local, State, and Federal guidelines for how antifreeze is in fact recycled and disposed of, and it is the Jiffy Lubes that are abiding by those considerations.

To your first question, I wish there was a reporting requirement for both pets and people in the State of California around this issue, but due to concerns about appropriations associated with that component, it was removed from the bill. And, sir, if I may, just one more point that has troubled me a little bit today. With all due respect to the call for a regulatory process to consider the viability of DB in antifreeze, that study has been done. That was done by CPSC, which made a recommendation that it in fact be included in a number of common household products, including antifreeze.

MR. SULLIVAN. Thank you.

MR. GILLMOR. That concludes our hearing, and I want to thank all of our witnesses for coming. Testimony is very helpful. We stand adjourned.

[Whereupon, at 4:01 p.m., the subcommittee was adjourned.]

## RESPONSE FOR THE RECORD BY DR. MELINDA EYRICH, DVM, CO-OWNER, URGENT CARE VETERINARIAN HOSPITAL

June 26, 2006

The Honorable Paul E. Gillmor, Chairman Subcommittee on Environment and Hazardous Materials Committee on Energy and Commerce 2125 Rayburn House Office Building Washington, DC 20515

Dear Mr. Chairman,

Thank you for your questions. I am happy to see the interest and investigation continuing on the Antifreeze Bittering Act of 2005, H.R. 2567. Any continuing effort to lessen the danger of antifreeze is greatly appreciated by those of us trying to deal with its effects.

Sincerely,

Melinda S. Eyrich DVM Urgent Care Veterinary Hospital 9032 Montgomery Blvd Albuquerque, NM 87108

#### THE HONORABLE PAUL E. GILLMOR

1. New Mexico has been one of three states to actually require DB in antifreeze products. Could you please describe for me how the implementation of this new law has changed, if at all, the number of animals you have had to see as a result of antifreeze ingestion?

Governor Richardson signed the bill into law in April 2005, manufacturers were required to add DB beginning July 2005, and retailers were required to sell bitter antifreeze on January 1, 2006. While the bittering mandate is new and its effects are not yet fully known, I have not seen a case of antifreeze poisoning in 2006. If the trend continues, 2006 will be a year to both remember and celebrate!

2. In your professional opinion, at the levels required in the New Mexico state law and the legislation before the Committee today, would DB by itself present a serious health risk to pets or humans from ingestion?

Based on the testimony given during the hearing the following facts were evident to me: DB has been in use as a taste deterrent since approximately 1964. Since that time, no adverse effects of this chemical have been found. After the hearing, I looked through both my home and clinic and found no less than twelve items with DB added to them. These items include cleaning products I use to clean the bath tub I bathe my four year old in and fingernail polish remover my teenager uses regularly. I know that both animal and people do not like very bitter tastes. I feel that DB is a far safer risk than antifreeze. I know antifreeze kills, so far DB has not caused any detectable problems.

3. You mention that one vial of the drug used to treat for ingestion of ethylene glycol costs about \$300. How many vials are normally required for treatment and how much would a person expect to pay to simply restore their pet's health after ingestion of antifreeze?

Depending on the size of the animal, 1-3 vials would be needed. With early detection and treatment, the conservative estimate is 1200.00 to 1500.00 dollars. If there are complications associated with kidney failure, the estimated cost could be 2000.00 and up. This is a significant financial burden for most families and for a significant number treatment is financially prohibitive.

## RESPONSE FOR THE RECORD BY SARAH AMUNDSON, DEPUTY AND LEGISLATIVE DIRECTOR, DORIS DAY ANIMAL LEAGUE

June 28, 2006

Honorable Paul E. Gillmor Chairman, Subcommittee on Environment and Hazardous Materials Committee on Energy and Commerce U.S. House of Representatives 2323 Rayburn House Office Building Washington, D.C. 20515-6115

Dear Mr. Chairman:

We are pleased to have the opportunity to respond to your additional questions, as well as those submitted by Committee Ranking Member John Dingell and Subcommittee Ranking Member Hilda Solis, as part of the hearing record on H.R. 2567, the *Antifreeze Bittering Act*.

Thank you for holding the hearing on this important bill. Please let us know how we can be of further assistance.

Sincerely,

Sara Amundson Legislative Director

SA/nb

Submitted Questions from Members Subcommittee on Environment and Hazardous Materials Hearing on HR 2567, the "*Antifreeze Bittering Act of 2005*," May 23, 2006

### Sara Amundson, Legislative Director, Doris Day Animal League

From the Honorable Paul Gillmor, Chairman, Subcommittee on Environment and Hazardous Materials

1. Your testimony states that unlike MTBE liability protection that was debated during the Energy Policy Act of 2006, the liability protection in HR 2567 establishes an "assigned" liability scheme where each manufacturer remains entirely on the hook for their respective product. Can you explain how this

scheme theoretically would work when a court is assigning damages based on antifreeze contamination?

The antifreeze manufacturers would remain liable for damages associated with their product. Denatonium benzoate (DB) is a very distinct chemical and the manufacturers of that product would remain liable for damages caused by it. A court would assign damages based on the damages caused by each product separately. This is no different from assigning liability in any other case where multiple contaminants might be released at the same location, and a court must assign liability based on the damages caused by each contaminant separately. For example, where one party might have released petroleum products at a site and another party might have released a chlorinated solvent at the same site, a court would impose liability on each party for damages caused by the material it released.

2. Does your organization see either the antifreeze manufacturers or the DB manufacturers as being unfairly advantaged by the inclusion of the liability protection? How has your group worked with the environmental organizations and the water utilities at the state level regarding the liability provisions? Are you aware of any reported contamination cases of DB from antifreeze in the states that have passed legislation?

No. The purpose behind crafting this provision in the way in which it was done was to ensure that the manufacturers of antifreeze and the manufacturers of denatonium benzoate (DB) would be responsible without limit for correcting any problems and remediating any damage caused by their respective products.

The Natural Resources Defense Council and the World Wildlife Fund actually endorsed H.R. 1563 in the 108th Congress, and that bill did include liability language. While that language differed from the current bill, it did cover "personal injury, death, or property damage that results from the inclusion of denatonium benzoate in ethylene glycol antifreeze, provided that the inclusion of denatonium benzoate is in concentrations mandated" under the bill. It has been argued that "property damage" could also have encompassed environmental damage. I would also note that the California Sierra Club supported the bill that went on to become law there, and the Sierra Club Rio Grande chapter in New Mexico supported the bill that became law there, the liability language in which is identical to that in H.R. 2567.

We are not aware of any reported contamination cases involving DB in antifreeze in the states that have passed legislation. As a matter of fact, both Oregon and California have stated that they have not observed any ill effects on water supplies. As noted in my testimony, a report by the Maine Department of Environmental Protection cited a conversation with Ken Kaufmann, Oregon's state toxicologist, in which he stated that "'no incidents of drinking water well contam-ination or groundwater contamination or bad tasting water due to denatonium benzoate have become known." Likewise, a letter from the California State Water Resources Control Board to the subcommittee noted that "to date we are unaware of adverse impacts to California's water supplies arising from the use of denatonium benzoate in antifreeze and a variety of other products." (New Mexico's law has been in effect for only a little over a year.) I think Cong. Wilson's question to Mr. Bonacquisti, who testified on behalf of the American Water Works Association, got to the crux of the matter: Mr. Bonacquisti could not cite any cases of water contamination from DB, even though it has been used in a variety of products for over 40 years. 3. What happens under the liability provisions if one of the manufacturers or distributors is grossly negligent or malfeasant in the handling and disposing of antifreeze? What about a user or consumer? Are any absolved from liability in any way under these provisions?

Our interpretation of the bill's liability language, which states that the liability limitation applies only insofar as "the inclusion of denatonium benzoate is present in concentrations mandated by" the bill and that "limitation on liability...does not apply to a particular liability to the extent that the cause of such liability is unrelated to the inclusion of denatonium benzoate in any engine coolant or antifreeze," and our intention, has been that any use or handling of DB by the antifreeze industry that does not comply with the law would not be covered. This would include, of course, any negligence or malfeasance on their part. However, we appreciate that some have viewed the provision as deficient with regard to "willful misconduct," and we certainly are amenable to including a specific exception to the liability provision for "willful misconduct."

The "limitation on liability" applies only to "a manufacturer, processor, distributor, recycler, or seller of an engine coolant or antifreeze"; the legislation does not address consumer mishandling or improper disposal of antifreeze. Localities generally regulate, or otherwise provide guidance to residents on, the proper disposal of household chemicals.

4. In your testimony you admit that there are data gaps for hazard identification. These data gaps, if significant enough, could prevent a thorough risk analysis. If DB has been in use for over forty years, why are there any data gaps at all?

The Doris Day Animal League would defer any conclusions regarding a thorough risk analysis of denatonium benzoate or ethylene glycol to the federal regulatory agencies responsible for assessing available information and regulating these respective chemicals. Relevant to denatonium benzoate is the testimony of Jim Willis of the Office of Pollution Prevention and Toxic Substances of the Environmental Protection Agency, who, through available data and further modeling studies, provided chemical structure background specific to environmental exposure, human/wildlife exposure, human/wildlife toxicity, and aquatic toxicity.

During questioning, Mr. Willis responded that EPA had not conducted testing of Bitrex (one of the commercially available brands of denatonium benzoate) because, based on a review of available data and experience with similar chemicals and other analogies, such testing was not necessary. In response to another, similar question, he noted that, more generally, with respect to a chemical of this nature, with this production volume and exposure, EPA would determine that a full risk assessment was not warranted.

5. Why don't educational campaigns prevent most of the accidental ingestions? How have the additional protective measures such as labeling, child proof caps and education failed? Is there anything that can be done in terms of an educational campaign to raise awareness even more that may help to reduce accidental ingestions?

I would preface my response to this question by noting that animal poisonings and deaths, both in sheer numbers and as a percentage of ingestions, far exceed those of humans. The packaging, labeling, and educational efforts of the antifreeze industry don't mean much when a dog can and will chew through a container, or a disgruntled neighbor

takes out his anger on the cats next door. As we noted in our testimony, the estimates of such poisonings run from a low of 10,000 to as high as 90,000 deaths per year.

We recognize the antifreeze industry for its proactive efforts to safeguard human health with respect to the use and misuse of its products. To reduce the risks of accidental exposure, all antifreeze products sold to consumers are equipped with childresistant caps and provide prominent label warnings about proper use, storage, and disposal of the product. In addition, most manufacturers, including Prestone, adhere to a voluntary industry policy to use foil safety seals on consumer product containers.

Between 1983, when the American Association of Poison Control Centers began collecting such data, and 2004, there were no reported deaths of children under the age of six. Unfortunately, there has been such a death this year: According to <u>The Advocate</u>, a Louisiana newspaper, on May 31, a three-year-old Baton Rouge boy died after drinking antifreeze left in a cup on a bedroom dresser by his father's girlfriend. The intended use of the antifreeze was to poison some dogs hanging around the house. The woman was booked on one count of negligent homicide.

Deaths of children between 6 and 19 years of age have been primarily teenage suicides, as have many deaths among adults, although some have been homicides. Antifreeze is an easy, and easily obtained, weapon for homicide or suicide; the addition of denatonium benzoate would make antifreeze far less appealing for these purposes.

Since 2000, the reported number of ethylene-glycol antifreeze poisoning exposures, of children specifically and in general, have held fairly steady (about 1300 and 5000 respectively). We would argue that those numbers are still too high—and unnecessarily high when there is an inexpensive additional step that can be taken to reduce the number and severity of ingestions among both humans and animals. Educational campaigns likely reach a point of maximum effectiveness, and it is not possible to put a complete end to human carelessness and indifference, or determination to harm one's self or others. Moreover, educational campaigns and child safety caps do not discourage pets from licking up the spills that still occur despite industry's best efforts to prevent them, or keep dogs from chewing through containers, nor do they dissuade individuals from using antifreeze to deliberately kill animals or other people, or to commit suicide.

The use of a bittering agent in antifreeze would provide an inexpensive additional layer of protection against accidental ingestions, and make it less attractive as a suicide method or as a weapon to use against animals and humans alike.

Submitted Questions from Members Subcommittee on Environment and Hazardous Materials Hearing on HR 2567, the "*Antifreeze Bittering Act of 2005*," May 23, 2006

Sara Amundson, Legislative Director, Doris Day Animal League

From the Honorable John Dingell, Ranking Member, Committee on Energy and Commerce, and the Honorable Hilda Solis, Ranking Member, Subcommittee on Environment and Hazardous Materials

1. Your testimony stated that denatonium benzoate (DB) is added to "cosmetic and toiletry products, including nail polish, hairspray, and cleaners."

Have the manufacturers, processors, distributors or recyclers of cosmetic and toiletry products, including nail polish and hairspray, been granted immunity from liability for damage to the environment (including natural resources) that results from the inclusion of denatonium benzoate in these products? If so, please cite the specific Federal law that

provides liability immunity for "damage to the environment (including natural resources)" to the manufacturers, processors, distributors, or recyclers of such products. Not to our knowledge.

2. Do the manufacturers, processors, distributors, recyclers, or sellers of nail polish, hairspray, or other cosmetic products that include denatonium benzoate in their products receive immunity from liability for personal injury, death, property damage, or economic loss that results from the inclusion of denatonium benzoate in the product? If so please cite the specific Federal law that provides such immunity from liability.

Not to our knowledge.

3. Are there any scientifically-valid statistics gathered by the State or an animal poison control center that provide information on whether and to what degree the Oregon or California laws have led to a reduction in accidental ethylene glycol poisonings in dogs and cats? If so, please provide them.

No such data have been collected. This is a glaring shortcoming of the Mullins and Horowitz review that was published in 2004 (as referenced in my testimony), since the overwhelming problem with antifreeze poisonings, in terms of the number of both ingestions and deaths, occurs with companion animals. We know of no state or other requirement for reporting cases of ani-mal poisonings. In fact, as part of its antifreeze bittering bill, California opted *not* to appropriate funds to collect data on animal poisonings. Moreover, the data that the national animal poison control center has on these incidents are somewhat misleading: It is acknowledged that, since veterinarians see antifreeze poisoning cases so frequently, they know what to do and most do not even bother to call the center.

4. Does the Doris Day Animal League believe that ethylene glycol antifreeze is an inherently dangerous product?

The Doris Day Animal League relies upon the characterization of ethylene glycol by the Environmental Protection Agency in its Integrated Risk Information System, and by the Agency for Toxic Substances and Disease Registry's "Toxicological Profile for Ethylene Glycol and Propylene Glycol," for acute and chronic effects.

5. Is the Doris Day Animal League aware of any lawsuits that have been brought against Honeywell or other manufacturers of antifreeze in 2004 or 2005 for accidental antifreeze poisoning due to ingestion of ethylene glycol that caused death to a dog or cat? If so, please indicate the number of such lawsuits in 2004 and 2005 and the legal theory behind the lawsuit.

No, we are not.

6. Subcommittee Chairman Gillmor, in questioning a witness about balancing risks, stated at the hearing that:

"We know on one side there is a risk of death to children, and if Mr. Ackerman's testimony is correct, 1,400 children a year, that means on average we have more than 100 children every month dying from the lack of a bitterant in antifreeze."

Do you agree or disagree with the statement that "we have more than 100 children every month dying from the lack of a bitterant in antifreeze"?

There was a bit of a misunderstanding. Rep. Ackerman referred to approximately 1400 children each year who are poisoned by antifreeze (with children defined as persons 19 years of age and under). This number refers to ingestions, not deaths. Rep. Wilson clarified this later in the hearing. The number of deaths of children over time has been relatively small, though it may be said that any is too many. And unfortunately, a 3-year-old boy in Louisiana died this past May after drinking antifreeze that had been left in a cup on a dresser; the antifreeze was going to be used to poison dogs. Deaths of children between 6 and 19 years of age have been primarily teenage suicides; the presence of a bitterant in antifreeze would discourage at least some of these rash teenagers from using it to kill themselves.

### If I may, I would like to respond to questions #7 and #8 together:

 Are you aware of a 2005 study by a group of doctors led by Dr. E. Martin Caravati conducted on behalf of the American Association of Poison Control Centers, Washington, D.C., and published in Clinical Toxicology Journal, which made the following statements:

"A review of U.S. poison center fatality data for the 18-year period 1985-2002 did not find any suspected suicides or deaths from ethylene glycol reported in children under the age of 12 years."

"No deaths of patients under the age of 12 years or from unintentional exposure were reported by poison centers to TESS (Toxic Exposure Surveillance System) from 1985-2002"?

If you have any information that supports or conflicts with these findings, please provide it.

8. In your testimony, you indicate that more than 1,300 children ingest antifreeze each year. What percentage had moderate or major effects? Are you aware that the E. M. Caravati et al. study found that for known outcome by reason for ingestion of ethylene glycol for all ages between 2000-2002, only 4 percent of the unintentional exposures had moderate or major effects?

The Doris Day Animal League was pleased to note the findings in the 2005 study by Dr. E. Martin Caravati, which concurred with conclusions we have seen and noted in reference materials from other studies of antifreeze ingestions by children under 12; notably, that no children in that age range have died from ingestions during the time period examined. Unfor-tunately, on May 31 of this year, in Baton Rouge, Louisiana, a three-year-old child did from ingesting antifreeze, which was stored in a cup on the parent's dresser to be used to kill nuisance dogs in the neighborhood. This is particularly tragic because it illustrates one horrific aspect of the problem all too well; by using antifreeze as a tool to kill dogs and improperly storing the chemical, a child also unnecessarily died.

The Caravati study also concludes that "only 4 percent of the unintentional exposures had moderate or major effect." That still represents approximately 52 people experiencing moderate to major effects every year, and we contend that if even one of those is a child, that is one child too many. The financial and emotional toll on a family from rushing a child to the emergency room to prevent renal failure and other complications is unacceptable in our society.

Moreover, with respect to the number of persons who ingest antifreeze and experience moderate to major effects, DDAL would suggest that it is somewhat disingenuous to exclude intentional ingestions, since these would not occur if antifreeze were not such an attractive suicide method. In 2003, across all antifreeze-related cases, the percentage experiencing moderate to major effects, or death, was 9.5 percent; in 2004, it was 11.5 percent, according to AAPCC statistics. As I have stated elsewhere and will expand upon later in response to another question, animal poisonings and deaths, both in sheer numbers and as a percentage of ingestions, far exceed those of humans. These numbers more than warrant taking this step to make anti-freeze taste bad and thus be less attractive to animals, children, potential suicides, and potential murderers.

9. In your prepared testimony submitted to the Subcommittee, you cited a California Integrated Waste Management Board (CIWMB) staff analysis as follows:

"The CIWMB staff analysis found that DB 'readily biodegrades, its transport is attenuated by soil, and it is easily treated in sewage treatment systems and drinking water systems. Staff has determined that the addition of [DB] to antifreeze would not lead to any adverse health or environmental effects.""

The CIWMB does not identify any scientific studies upon which these statements are based or discuss the body of scientific studies that have been performed that reached a different conclusion. Are you aware of whether the CIWMB staff performed any scientific studies or whether the CIWMB contracted for any scientific studies on the environmental fate and transport of DB? If you are aware of any such studies performed by the CIWMB staff or on behalf of the CIWMB, please provide them. Further, can you inform the Subcommittee whether the CIWMB ever explained in their report or elsewhere on what basis the staff was able to reach these scientific conclusions?

The California Integrated Waste Management Board, appointed by the governor, released this staff analysis in 2001, leading to the board's support of the California legislation. Ms. Anna Ward was the staff person assigned to compile the report. The Doris Day Animal League respectfully suggests that any questions regarding the studies used or commissioned would be more appropriately directed to the California Integrated Waste Management Board.

### If I may, I would like to combine questions #10, 11, and 12 for purposes of responding:

10. In your prepared testimony you state that, "the Washington State School of Veterinary Medicine places the annual number of dog and cat antifreeze poisonings at approximately 10,000."

Is the figure based on an actual statistically significant study? If not, what is the figure based on? Does the term "poisonings" in your testimony mean exposures or actual deaths?

- 11. Your prepared testimony also referred to a 1996 study of small practice veterinarians throughout the United States that found 90,000 dog and cat deaths each year from ingesting ethylene glycol. Was this a statistically significant study? How was it performed and by whom? Has there been a more recent comparable study?
- 12. What accounts for the significant disparity in numbers between the Washington State School of Veterinary Medicine estimate and the 1996 study?

When we refer to numbers of *poisonings*, we are referring to ingestions. When we say deaths, we are referring to actual deaths.

There are two national estimates of the number of companion animals who ingest antifreeze each year. One estimate cited frequently by a variety of sources puts the number of dogs and cats poisoned each year by antifreeze at 10,000. That number is attributed to the Washington State School of Veterinary Medicine. We do not know the source of their data.

The higher estimate of 118,000 exposures and 90,000+ DEATHS of dogs and cats due to antifreeze poisoning comes from a 1996 survey of "a nationally representative cross-section of small-animal veterinarians" (total number = 400) conducted by Bruno and Ridgway Research Associates on behalf of the American Society for the Prevention of Cruelty to Animals (ASPCA) and Safe Brands Corp. While we cannot account for the difference between the Washington State University statistics and the ASPCA survey results, more recent studies support the ASPCA results. A 2002 survey of 21 Nevada pet clinics revealed 78 cases of ethylene glycol poisonings, with 67 deaths (a fatality rate of 85 percent). A similar survey in 2001 of 13 California veterinary clinics reported 136 cases, with 107 deaths (a 78 percent fatality rate). These death rates are consistent with the 77 percent rate found in the 1996 survey.

## RESPONSE FOR THE RECORD BY PATRICE L. SIMMS, SENIOR PROJECT ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL

Honorable Mr. Paul E. Gillmor U.S. House of Representatives Chairman, Subcommittee on Environment and Hazardous Materials Committee on Energy and Commerce

Dear Mr. Gillmor:

Thank you for the opportunity to testify before the Subcommittee on Environment and Hazardous Materials on Tuesday, May 23, 2006, regarding H.R. 2567, the Antifreeze Bittering Act of 2005. Attached please find answers to the follow-up questions that you forwarded to me by letter dated June 8, 2006.

Sincerely,

Patrice Simms Senior Project Attorney Natural Resources Defense Council

### Questions from the Honorable Paul E. Gillmor

 Legislative bodies make value judgments all the time substituting one risk for another in pursuit of the common good. Do you think that it is fair or appropriate for a person or entity, pursuant to a Federal mandate, to fully comply with the law in making their product and then be liable for damages if an unrelated person or entity is negligent in the use of that product?

In general, NRDC believes that it is both fair an appropriate to hold manufacturers of a dangerous product accountable for the injuries that their product causes, including injuries that are associated with any additive that is necessary to make their product safer. To the extent that any individual injury results in part from the activities of "an unrelated person or entity [who] is negligent in the use of that product," that person should also bear liability. It is entirely inappropriate, however, to provide a wholesale waiver of liability for any possible harm for the very industry involved in the production and sale of a dangerously toxic product. Injured parties should have full access to the courts, and the ability to seek restitution from *each and every* responsible party.

2. Why are you opposed to the liability protection included in this bill when the manufacturers of both products are completely held accountable for their own products? By opposing this provision, are you arguing that the deeper pockets should always be available to pay for damages, even when their product is not legally found to be the cause of the contamination or damage? Is assigned liability a new concept or do the courts engage in this practice all the time?

### 125

The liability waiver provision of H.R. 2567 rests upon a convenient fiction that each manufacturer (the maker of the bitterant and the maker of the antifreeze) should be responsible for the possible ill-effects of its own product. The underlying presumption being that the antifreeze manufacturers are responsible for the presence and impact of their product in the marketplace and the manufacturers of the bitterants are responsible for their product. However, this fiction ignores entirely the fact that *but for* the unacceptably dangerous nature of the antifreeze itself, the bitterant would be an unnecessary ingredient and would not be in the marketplace in this product at all. In fact, the manufacturers of the bitterant are not responsible for creating the need for their product in antifreeze, and thus should not be, as the bill suggests, uniquely and exclusively responsible for the risks associated with this particular use of their product.

Congress is considering a bitterant requirement for antifreeze because the product that the antifreeze manufacturers make (in the view of this bill's sponsors) is unacceptably unsafe. Thus, it is due to the dangerousness of the antifreeze (the product that antifreeze manufacturers profit from) that a bitterant may be required, and yet Congress is considering letting antifreeze manufacturers off the hook entirely for any damage that might result from the use of a bitterant in their product. This approach would take away significant rights from those people who might be harmed in the future by this bitterant use – the right to seek redress against the industry sector that is both responsible for creating the need for the bitterant and that profits from the sale of the otherwise dangerous product. Accordingly, antifreeze manufactures, as the makers of a dangerous product, must be held responsible (along with the bitterant makers) for the consequences of introducing a bitterant into the marketplace in antifreeze, and therefore should bear their share of the risk associated with possible injury or environmental contamination.

The process of assigning liability among responsible parties, to the extent that this is necessary at all, should occur in the courts, where the relevant, case-specific factors can be taken into consideration. RESPONSE FOR THE RECORD BY JEFFREY BYE, VICE PRESIDENT, PRESTONE, HONEYWELL INTERNATIONAL, INC., ON BEHALF OF CONSUMER SPECIALTY PRODUCTS ASSOCIATION

> Submitted Questions from Members Subcommittee on Environment and Hazardous Materials Hearing on HR 2567, the "Antifreeze Bittering Act of 2005" Jeffrey Bye, Vice President, Prestone

#### The Honorable Paul E. Gillmor

# 1. How much of the domestic antifreeze industry does Prestone supply? Who are your other competitors in the field? Do all U.S. antifreeze suppliers have the same position on this bill?

Prestone is the largest antifreeze manufacturer in North America, supplying approximately one-third of the 160 million gallons sold to American consumers. There are four other major market players in the U.S. consumer antifreeze industry: Old World, Shell, Valvoline, and Chevron Texaco.

All U.S. antifreeze manufacturers support HR 2567, the Antifreeze Bittering Act of 2005.

2. Your company has vigorously opposed legislation like this in the past. Now, you are testifying in support of it. What changed and why is it so important to you to have these changes? Couldn't you support this bill without the environmental liability protections in it? Would you support changes to the bill to preclude liability protections for gross negligence or willful misconduct?

Prestone has historically opposed state and federal legislative efforts to require antifreeze manufacturers to reformulate and add ingredients to our products that we do not produce nor have a heating or cooling function. Because of the growing trend of states both passing laws and considering legislation that would mandate our adding a bittering agent to ethylene glycol antifreeze, in 2004 the industry reconsidered its position.

Existing state laws in Oregon, California and New Mexico vary to some extent, and our concern is that additional states will pass incompatible requirements, denying us the ability to efficiently produce a low-cost effective product sold throughout the nation. The federal legislation currently under consideration by the House Energy and Commerce Committee, HR 2567, includes provisions to allocate liability between the antifreeze and bittering agent manufacturers. The antifreeze industry supports the legislation because we are comfortable with retaining responsibility for our own ethylene glycol products, and we recognize the equity in assigning responsibility for the denatonium benzoate to its manufacturer.

HR 2567 also establishes a prescribed standard of the type of bittering agent and concentration, thus setting a uniform national standard. Because of these changes, we support the bill as introduced. We would not support the legislation without the assigned liability provisions and standardized prescription.

The provision in question limits liability only for damages that result from the inclusion of denatonium benzoate in antifreeze in accordance with the terms of the statute. An antifreeze manufacturer would be responsible for action or inaction outside the scope of the limited set of circumstances outlined by the bill. Given the mandate included in HR 2567, it is not apparent how such inclusion of denatonium benzoate could be grossly negligent or amount to willful misconduct. Accordingly, we do not see the

rationale for a change that would limit the protection in cases of gross negligence or willful misconduct, and are concerned that such a change would be confusing.

3. Your testimony admits that a major ingredient in antifreeze is a toxic substance. Some people have argued that by creating a "causation" standard for environmental liability, you are somehow "muddying the water" on exactly how much your company should be responsible for cleanup of antifreeze releases into the environment. How do you respond to that charge?

Prestone has been making ethylene glycol antifreeze for over 70 years and we whole-heartedly take responsibility for our product. We understand how our product quickly breaks down in the environment and we would retain liability for damages caused by ethylene glycol under HR 2567. This legislation espouses sound public policy by allocating liability for ethylene glycol and denatonium benzoate to their respective manufacturers.

4. The legislation you are testifying about today could pre-empt states that have already acted and might be more regulation than some states want to impose. In addition to California, Oregon and New Mexico, your testimony speaks to 11 other states actively considering similar state laws. Are any municipalities also considering ordinances on this subject? Why should Congress act on this if so many jurisdictions are enacting fairly similar laws?

Many states are considering legislation along the same lines as Oregon, California and New Mexico, but none of the bills is identical to another. Antifreeze sold in onegallon containers is a classic retail consumer product, with the major "big box" retailers like Wal-Mart and AutoZone selling most of our products. Because manufacturers like Prestone don't control the distribution and inventory systems of our retailers, forcing us to make, store, transport and track state-specific formulas is not just onerous but also out of our control. Now is the time for Congress to pass a uniform federal standard before other states pass inconsistent laws. Even some municipalities within states have added to our concerns, with cities and counties in the state of New Mexico passing regulations specific only to their jurisdictions.

Significant stakeholders, including the U.S. Conference of Mayors, the Natural Resources Committee of the Maine state legislature, the Alabama House of Representatives, and the Tennessee Senate have recognized that products in interstate commerce are best governed by federal standards, and have called on Congress to pass legislation establishing a uniform bittering law for ethylene glycol.

5. Do you believe DB is the best aversive agent to prevent human or animal ingestion of your product? If not, do you believe there are equally effective and potentially less expensive alternatives? Recognizing the animal health consequences of ingesting antifreeze, why doesn't Prestone voluntarily place DB in its antifreeze products?

Prestone does not manufacture bittering agents and is not an expert on bittering additives or other agents that are not part of the heating and cooling functions of our products. Our understanding of DB, therefore, is based only on third party statements. DB is consistently regarded as the "bitterest substance on earth," and only a minimal amount is required to bitter antifreeze. At this time, we know of no other additive with the same bittering qualities. We have conducted studies on the effect of bittered antifreeze on automobile engines and have determined that DB does not cause corrosion. An alternative that would require a greater volume to achieve the same degree of bitterness may be more expensive because of the amount involved, as well as the potential damage to the automobile engine.

Prestone is the market leader in automobile heating and cooling products and we have no expertise with bittering agents or animal health issues. We would not voluntarily add denatonium benzoate to our products.

Our efforts to discourage accidental animal ingestion are well-documented and respected. During the past ten years, antifreeze manufacturers have supported the American Association of Poison Control Centers in a series of public service announcements entitled "Take Care: Car Fluids, Children and Pets." These public service anouncements also help to educate consumers about proper use and storage of antifreeze and other automobile fluids. Prestone and other antifreeze manufacturers sponsor a national poison control center as a resource and service for veterinarians and pet owners. The center is staffed with specially trained veterinary toxicologists available to handle any animal poison-related emergency, 24 hours a day, 365 days a year.

# 6. As I understand it, the only difference between HR 2567 and its version in the last Congress is that this year's bill contains a shield against environmental liability and economic loss. Is that correct? How do these new criteria change the bill from its previous reference to "property damage" and "personal injury"?

There are two significant differences in the liability provisions between HR 2567 and the version from the previous Congress. First, as you noted, is the addition of specific categories of liability protections, including natural resources. Although this term is arguably contained in the broader category of "property" included in the bill in the 108<sup>th</sup> Congress, we encouraged the bill sponsors to be more explicit in the description of the liability protections as they updated the legislation for the current 109<sup>th</sup> Congress.

The second significant difference in the bills' liability provisions is the establishment of assigned liability in HR 2567 between the manufacturers of ethylene glycol antifreeze and denatonium benzoate bittering agent. In the previous federal legislation, as well as the California and Oregon state laws, the liability protections regarding DB extend to all parties. The New Mexico law and HR 2567 include an allocation of liability provision that delineates responsibility between antifreeze and DB manufacturers respectively for their own products, offering a more comprehensive responsibility structure.

7. I am confused on your exact stance on the liability provisions in HR 2567 based on conflicts between your written testimony and your oral testimony. Could you please clarify for me Prestone and CPSA's stances on the liability shields in HR 2567? Does this language remove all rights of action against you? Would a harmed party be able to recover damages from antifreeze manufacturers?

Prestone and the U.S. antifreeze industry firmly support the liability provisions in HR 2567 and would oppose the legislation without them. The provisions allocate liability responsibility between antifreeze and DB manufacturers respectively, therefore, Prestone remains fully responsible for all consequences of our ethylene glycol antifreeze products. Parties in litigation could recover damages from antifreeze manufacturers for harm caused by the antifreeze, while parties could recover damages from denatonium benzoate manufacturers and distributors for harm caused by denatonium benzoate.

8. Would you support language in the bill explicitly clarifying that no liability protection can be extended for claims involving gross negligence or willful misconduct?

The liability provision in HR 2567 limits liability only for damages that result from the inclusion of denatonium benzoate in antifreeze in accordance with the terms of the statute. An antifreeze manufacturer would be responsible for action or inaction outside the scope of the limited set of circumstances. Given the mandate included in HR 2567, it is not apparent how such inclusion of denatonium benzoate could be grossly negligent or amount to willful misconduct. Accordingly, we do not see the rationale for a change that would limit the protection in cases of gross negligence or willful misconduct, and are concerned that such a change would be confusing.

#### The Honorable John Sullivan

1. During the hearing, in response to a question from Mr. Inslee, I thought you suggested that Prestone would continue selling antifreeze if the liability section was stripped from the bill. Would you please clarify that for me? In addition, could you please tell me what the impact of this mandate would be on the affordability of your product? How many other domestic manufacturers are there and would they be able to easily absorb the cost of this mandate? How many foreign based manufacturers of antifreeze, who sell their product in the U.S. market, would be economically advantaged by compliance with this mandate without the chance to be sued for damages?

Prestone would expect to continue selling antifreeze if the liability section was stripped from the bill, although we would no longer support the legislation. The liability provisions within HR 2567 are consistent with state laws and should remain part of the federal bill. While the price of antifreeze could be increased to cover potential costs associated with legal claims and liability related to sales of compliant product, it is also possible that continued sales and availability of antifreeze to consumers in the U.S. could be affected.

Although Honeywell is the market leader in consumer antifreeze products, there are four additional major domestic manufacturers. These companies are also represented by the Consumer Specialty Products Association and oppose the legislation absent the liability provisions. Foreign manufacturers who sell antifreeze in the U.S. would be covered under the proposed legislation and would maintain the same liability as U.S. manufacturers. Because the U.S. manufacturers satisfy approximately 95% of the U.S. market, foreign manufacturers are minimal players.

2. During the hearing, in response to another question from Mr. Inslee, I thought you suggested that citizens are better off if we preserve their right to go to court and that in order to do so we should strip the liability section from the bill. That doing so would ultimately protect children and animals. Could you please clarify my understanding of your response? Would the inclusion, or lack thereof, of the liability provisions in the bill preclude any physical protection to animals and children since the mandate would still be in place? Does HR 2567, as introduced, prevent citizens from going to the courthouse or preclude lawsuits for damages? Under the bill, if antifreeze is the cause of any personal or environmental harm, would any person be able to sue you for damages? Have you or your association tried to get environmental fate and transport information on DB? If you have tried and have been unsuccessful, do you believe that full compliance with the law, no matter who might agree with that law, should make your company and its assets eligible for damage suits over a

### component you did not choose to add, have little scientific information concerning it, and have no way of escaping its addition in your product?

The concept of "assigned liability" provides protection for citizens seeking to recover damages resulting from the use of a product. The antifreeze manufacturer would continue to be liable for their product and the DB manufacturer would be responsible for their product. Absent the liability protection, the antifreeze industry would oppose this legislation or any mandate for a bittering agent in antifreeze.

H.R. 2567 does not preclude citizens from going to the courthouse to seek damages. Parties in litigation could recover damages from antifreeze manufacturers for harm caused by the antifreeze, while parties could recover damages from denatonium benzoate manufacturers and distributors for harm caused by denatonium benzoate.

Prestone and CSPA, the industry association, have sought additional information on the transport and environmental fate of DB. To date, we have not received such data due to confidentially concerns of the DB manufacturers.

#### The Honorable John D. Dingell and the Honorable Hilda L. Solis

1. On July 28, 2004, an Op-Ed article by Consumer Specialty Products Association (CSPA) President Chris Cathcart entitled "Effectiveness, Safety of Bitterant Antifreeze Unknown" appeared in the Albuquerque Journal and stated as follows:

"According to the American Association of Poison Control Centers (AAPCC), virtually all deaths (22 nationwide in 2003) by antifreeze are intentional suicides. There has not been a death of a child under the age of 6 related to the accidental ingestion of antifreeze since the AAPCC began collecting data in 1983. Most exposures reported to the AAPCC are minor in nature."

### Do you agree with those written statements and does CSPA still stand behind them?

Prestone and CSPA stand behind the numbers stated in the editorial and referenced by the AAPCC. The AAPCC reported a total of 2,395,582 exposures to chemical substances in 2003. Of these, the AAPCC reported that it received a total of 5,816 reported exposures to ethylene glycol. Put in context, the total number of reported exposures to ethylene glycol amounts to 0.24% percent (i.e., less than one-quarter of one percent) of the total chemical exposures. In 2003, there were 19 deaths: 16 of the deaths were ruled intentional suicides, two deaths were of unknown causes (i.e., suicide could not be conclusively proven), and one death of an 81 year-old man was ruled as "unintentional general." This last case involved an elderly woman in New Jersey who poisoned her 81-year old companion by adding ethylene glycol to the man's drink.

For your information, AAPCC recently released their 2004 numbers. The AAPCC reported a total of 2,438,644 exposures to chemical substances in 2004. Of these, the AAPCC reported that it received a total of 5,562 reported exposures to antifreeze. The total number of reported exposures to ethylene glycol amounts to 0.228% percent (i.e., less than one-quarter of one percent) of the total chemical exposures. In 2004, there were 23 deaths: all of these cases were intentional ingestions and 19 were cases where the intention of the individual was to commit suicide.

We are pleased that you are asking about child poisonings and public health. The industry is extremely committed to protecting human health related to the use and misuse of our products. We have made significant strides in reducing child poisonings.

Unfortunately the recent increase in suicides and intentional murder is something that is difficult to combat. The AAPCC reports that there has not been a death of a child under the age of six related to ingestion of ethylene glycol-based automotive antifreeze since it began collecting data in 1983<sup>\*</sup>. The producers of antifreeze have also taken steps to reduce the risks from accidental exposure through the use of child-resistant closures. All antifreeze products sold to consumers are equipped with child-resistant closures and provide prominent label warnings about proper use, storage and disposal of the product. See 16 CFR § 1700.14(a)(11) and 16 CFR § 1500.14(b)(2). In addition, most manufacturers including Prestone adhere to a voluntary industry policy to use foil safety seals on consumer product containers. The AAPCC concluded that child-resistant closures have been extremely effective in preventing accidental exposures to consumer products.

2. In the same Op-Ed article in the Albuquerque Journal, the President of the CSPA stated:

"Not only is the effectiveness of mandating the use of a bittering agent in antifreeze questionable, there are also concerns about the impact of DB [denatonium benzoate] on the environment. Independent scientific studies have determined that DB does not biodegrade and is not removed during the processes used to treat wastewater at publicly owned treatment facilities. If poured onto the ground, DB could contaminate groundwater, potentially threatening public drinking water."

### Do you share the concerns expressed by the President of CSPA in his Op-Ed article to the Albuquerque Journal? If not, please explain why not.

Prestone, CSPA and the antifreeze industry have always been consistent in our position that the environmental fate of denatonium is uncertain. We understand the environmental impacts of ethylene glycol, but we do not manufacture DB and have limited knowledge on its chemical profile. The House legislation, therefore, rightfully distinguishes liability between the antifreeze manufacturers who maintain responsibility for ethylene glycol and the DB manufacturers who remain liable for their product.

Also, with regard to the OP-Ed piece, it is important to recognize that the CSPA response referred to a New Mexico bill that included a bittering mandate for all antifreeze products including quantities of 55 gallon non-consumer containers and larger. Because of the volume of antifreeze in these larger containers, the amount of DB would be proportionally larger as well. That was a significant concern of CSPA's with the 2003 version of the New Mexico bill. Like the current federal bill, however, the 2004 New Mexico legislation applied to one gallon consumer retail containers and had the support of CSPA and Prestone.

3. In your testimony to the Subcommittee you stated, "it is rare that children are accidentally exposed to antifreeze." Please provide your best estimate of the number of children accidentally exposed to antifreeze each year in the United States for the years 2003, 2004, and 2005.

<sup>\* &</sup>lt;u>The Advocate</u> (a Louisiana newspaper) reported that on May 31, 2006, a 3 year-old Baton Rouge boy died after drinking antifreeze left in a cup on a bedroom dresser by his father's girlfriend. The woman was booked on one count of negligent homicide. The antifreeze was reportedly intended for a neighbor's dog.

Prestone and the antifreeze industry rely on data from the American Association of Poison Control Centers (AAPCC). The AAPCC reports that there has not been a death of a child under the age of six related to ingestion of ethylene glycol antifreeze since it began collecting data in 1983<sup>\*</sup>. The producers of antifreeze have taken steps to reduce the risks of accidental exposure through the use of child-resistant closures, and the AAPCC concluded that such closures have been extremely effective in preventing accidental exposures. Consumer antifreeze products feature prominent label warnings about proper use, storage and disposal. In addition, most manufacturers including Prestone adhere to a voluntary industry policy to use foil safety seals on consumer product containers.

The AAPCC reported a total of 2,395,582 exposures to chemical substances in 2003. Of these, the AAPCC reported that it received a total of 5,816 reported exposures to ethylene glycol. The total number of reported exposures to ethylene glycol amounts to 0.24% percent (i.e., less than one-quarter of one percent) of the total chemical exposures. In 2003, there were 19 deaths caused by ethylene glycol: 16 of the deaths were ruled intentional suicides, two deaths were of unknown causes (i.e., suicide could not be conclusively proven), and one death of an 81 year-old man was ruled as "unintentional general." This last case involved an elderly woman in New Jersey who poisoned her 81-year old companion by adding ethylene glycol to the man's drink.

In 2003, there were 582 exposures to children under 6, and 803 to children between 6 and 19. In total, 1,385 of the 5,816 reported cases of exposure involved children under the age of 19.

For 2004, the AAPCC reported a total of 2,438,644 exposures to chemical substances. Of these, the AAPCC reported a total of 5,562 reported exposures to antifreeze. The total number of reported exposures to ethylene glycol amounts to 0.228% percent (i.e., less than one-quarter of one percent) of the total chemical exposures. In 2004, there were 23 deaths caused by ethylene glycol: all of these cases were intentional ingestions and 19 were cases where the intention of the individual was to commit suicide.

In 2004, there were 672 exposures to children under 6, and 678 to children between 6 and 19. In total, 1,350 of the 5,562 reported cases of exposure involved children under the age of 19.

The 2005 data has not been released.

4. Do you agree with the findings of Dr. Michael E. Mullins and Dr. B. Zane Horowitz in a published 2004 report on the Oregon law entitled "Was It necessary to Add Bitrex (Denatonium Benzoate) to Automotive Products" when they concluded:

'The first law mandating- addition of DB was never necessary. As unintentional EG or Meoh exposures in pre-school age children did not cause measurable toxicity. The mandatory addition of DB to automotive products has produced no measurable reduction in unintentional pediatric toxic alcohol exposures in Oregon."

We neither agree nor disagree with the findings of Drs. Mullins and Horowitz. Prestone and the antifreeze industry have reviewed and examined the effects of denatonium benzoate only as to its impact on an automobile engine. Ethylene glycol

<sup>\* &</sup>lt;u>The Advocate</u> (a Louisiana newspaper) reported that on May 31, 2006, a 3 year-old Baton Rouge boy died after drinking antifreeze left in a cup on a bedroom dresser by his father's girlfriend. The woman was booked on one count of negligent homicide. The antifreeze was reportedly intended for a neighbor's dog.

antifreeze containing DB in the quantities specified by the House bill will not corrode an engine.

We note that the primary goal of the federal legislation is to prevent the accidental ingestion of antifreeze by pets and other animals, with the deterrence of children's ingestion a secondary benefit. Drs. Mullins and Horowitz focused their study only on pediatric exposures.

# 5. Do you have any credible evidence that shows that the addition of DB produced a measurable reduction in unintentional pediatric toxic alcohol exposures in Oregon?

Prestone and the antifreeze industry have reviewed and examined the effects of denatonium benzoate as to its impact on an automobile engine. We have neither pursued nor do we possess evidence regarding the reduction in pediatric exposures as a result of the addition of DB to ethylene glycol products.

## 6. Do any States require reporting of accidental human exposures to antifreeze? If so, please identify them.

To our knowledge, no states require the reporting of accidental human exposures to antifreeze. However, the AAPCC compiles exposure data for all chemicals from 62 state and regional poison control centers. This data includes accidental exposures to antifreeze.

#### 7. Do any States require reporting of intentional human exposures to antifreeze? If so, please identify them.

To our knowledge, no states require the reporting of intentional human exposures to antifreeze. However, the AAPCC compiles exposure data for all chemicals from 62 state and regional poison control centers. This data includes intentional exposures to antifreeze.

## 8. Do any States require reporting of accidental household pet or other animal exposures to antifreeze? If so, please identify them.

We are not aware of any States requiring the reporting of accidental animal exposures to antifreeze.

9. In your testimony to the Subcommittee you stated, "there are occasions where household pets and other animals are exposed to ethylene glycol products and are injured by ingesting the product." Please provide the magnitude of the term "occasions" and provide any information you have on how many household pets and other animals die each year in the United States from ingesting antifreeze and how many are seriously injured? Please also provide the basis for the numbers you submit.

There are two national estimates of the number of companion animals who ingest antifreeze each year. One estimate that is cited frequently by a variety of sources is that 10,000 dogs and cats are poisoned each year by antifreeze. That number is attributed to the Washington State School of Veterinary Medicine. A higher estimate of 118,000 exposures and 90,000+ deaths of dogs and cats due to antifreeze poisoning is attributable to a survey conducted in 1996 by Bruno and Ridgway Research Associates on behalf of the ASPCA and Safe Brands Corp.

10. How many lawsuits were filed in each of the years 2003, 2004, and 2005 against Honeywell and Prestone for causing deaths to children from the ingestion of antifreeze? What is the legal theory behind any such lawsuit?

There were no lawsuits filed against Honeywell and Prestone for deaths to children from the ingestion of antifreeze in the time period requested.

11. How many lawsuits were filed in each of the years 2003, 2004, and 2005 against Honeywell and Prestone for causing death or serious injury to household pets or other animals from the accidental ingestion of antifreeze? What is the legal theory behind any such lawsuit?

There were no lawsuits filed against Honeywell and Prestone for deaths or injury to animals from the ingestion of antifreeze in the time period requested.

12. Is it correct, that in the fall of 2005 officials of the Consumer Specialty Product Association contacted staff members at the Environmental Protection Agency (EPA) and requested that they run a computer-based model for a potential risk profile for bitrex (denatonium benzoate) that relies on toxicity and environmental exposure estimation techniques?

Since the CSPA had accumulated numerous scientific studies on the environmental fate of denatonium benzoate, which they had submitted to the Congressional Research Service by letter dated September 24, 2004, did CSPA officials provide the same scientific studies to EPA so its review could be based on actual studies rather than computer models? If not, please explain why not.

In the fall of 2005, CSPA met with EPA officials to inquire if they had environmental fate data on DB. It is our understanding that CSPA did not ask EPA to run modeling studies, although EPA may have conducted studies either before or after the CSPA meeting at their own volition or after requests from stakeholders in Congress or elsewhere. CSPA has sought for many years conclusive environmental fate data of DB from various sources, although such data does not seem to be publicly available.

In an effort to be transparent on the issue, we understand that CSPA provided to the Library of Congress as well as the Majority and Minority staff of the House Energy and Commerce Committee all information that they had regarding DB. CSPA does not know whether the Majority or Minority staff shared that information with EPA.

13. On July 16, 2004, correspondence from CSPA to Macfarlan Smith Limited stated as follows:

"CSPA believes that there is no demonstrated scientific basis for these state and local requirements. Further, existing studies and records indicate that, with respect to those jurisdictions that have enacted such laws, there is no credible scientific evidence showing that the inclusion of bitterants in such automotive products has resulted in a reduction in incidents of accidental poisoning."

Do Honeywell and CSPA continue to believe there is "no demonstrated scientific basis for these state and local requirements" to mandate the inclusion of denatonium benzoate or other aversive agents in antifreeze? CSPA and Honeywell possess no scientific data to prove that the inclusion of denatonium benzoate in antifreeze will prevent accidental ingestion of antifreeze. Animal welfare advocates, however, believe that DB will help prevent animal ingestion of antifreeze. Furthermore, we continue to believe that individual state bills are not the best way to address the supporters request to mandate DB in ethylene glycol antifreeze, but instead we recommend a uniform federal solution.

The entire antifreeze industry is willing to add DB to their products, per the mandate of HR 2567, as an additional layer of safety to protect animals and humans as long as the liability and uniformity provisions are maintained in the legislation.

# 14. What specific factual circumstances with respect to the inclusion of denatonium benzoate in antifreeze cause Honeywell to believe that it is necessary to have the legal immunity as provided in Section 2 of H.R. 2567 from "damage to the environment (including natural resources)"?

Honeywell, under its Prestone brand, is the market leader in ethylene glycol and propylene glycol antifreeze products. We are not in the business of, studying, developing or manufacturing denatonium benzoate or other bittering agents. HR 2567 rightfully allocates the liability between the antifreeze and DB manufacturers for their respective products. The legislation would ensure injured parties the right to sue the appropriate manufacturer for all damages – including damage to the environment and natural resources – caused by that manufacturer's product.

This arrangement of assigned liability is appropriate because of the rare circumstance where the federal government is mandating the inclusion of a substance in a manufacturer's product.

15. If a manufacturer, distributor, or processor of antifreeze negligently spilled a gallon of denatonium benzoate that it intended to include or was in the process of including in engine coolant or antifreeze and it caused contamination of drinking water supplies or a groundwater aquifer, do you agree that the manufacturer, distributor, or processor would be immune from environmental liability under Section 2 of H.R. 2567? If not, please explain why not.

No, a manufacturer of antifreeze who negligently spilled DB in the manufacturing process would not be immune from environmental liability under HR 2567 for at least two reasons.

- The relevant statutory language in HR 2567 states that any manufacturer
  - "(1) Subject to paragraph (2), ... shall not be liable ... for any ... damage .... or loss that results from the inclusion of denatonium benzoate in any engine coolant or antifreeze, provided that the inclusion of denatonium benzoate is present in concentrations mandated by subsection (a).

(2) The limitation on liability provided in this subsection does not apply to a particular liability to the extent that the cause of such liability is unrelated to the inclusion of denatonium benzoate in any engine coolant or antifreeze."

In your scenario, you envision a manufacturer spilling a one gallon container of DB. First, because the liability in your fact pattern would stem from the manufacturer's negligence in handling the DB, subsection (2) of the liability section would explicitly prohibit protection because the liability is unrelated to the inclusion of denatonium benzoate in the antifreeze. Second, because the inclusion of DB in the antifreeze would far exceed the concentrations mandated by subsection (a) of the bill, 30 to 50 parts per million, the liability provisions would not protect the manufacturer.

A distributor or processor of antifreeze would not be in possession of DB because they only handle finished product, although our conclusion would be the same.

16. If a quantity of denatonium benzoate was spilled during the handling or distribution or during the formulation process by a manufacturer of antifreeze and caused damage to natural resources, would the natural resource trustee be able to bring an action under the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended, against the manufacturer for damage to the natural resources, or would such an action he precluded by Section 2 of H.R. 2567?

HR 2567 would not preclude an action under the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended.

17. Do you agree that all manufacturers of the bitterant denatonium benzoate are foreign manufacturers? If not, please identify any U.S. manufacturer and provide any evidence that you have demonstrating that a U.S. company is currently manufacturing denatonium benzoate.

No, not all manufacturers of DB are foreign. Honeywell Prestone buys its entire supply of DB for inclusion in ethylene glycol antifreeze (to satisfy the Oregon, California and New Mexico laws) from an Ohio manufacturer called PMC. We understand that PMC may contract manufacture the product from other domestic producers. Dragon Chemical, a subsidiary of Burlington Scientific, based in Farmingdale, New York, reportedly manufacturers DB as well.

For your information, the foreign manufacturers of DB would be liable for damages caused by their products sold in the United States. We have attached a memorandum from Arnold & Porter describing the scope of U.S. federal court jurisdiction to assist you in understanding the legal realities.

18. Do you agree that H.R. 2567 preempts State tort laws by providing immunity to manufacturers and sellers of engine coolant or antifreeze for injury, death, property damage, or damage to the environment resulting from adding a bittering agent, denatonium benzoate, to the coolant or antifreeze? If not, please explain why not.

HR 2567 would preempt state laws in so far as they differ from the federal regulation as set forth in the bill. State laws, tort and others, would continue to be effective in the regulation of antifreeze, or the regulation of bittering agents such as denatonium benzoate, just not state laws that attempt to regulate the inclusion of a bittering agent in engine coolant or antifreeze in retail containers under 55 gallons.

The relevant preemption provision in HR 2567 states:

"(d) Preemption- No State or political subdivision of a State shall have any authority either to establish or continue in effect with respect to retail containers containing less than 55 gallons of engine coolant or antifreeze any prohibition, limitation, standard or other requirement relating to the inclusion of a bittering agent in engine coolant or antifreeze that is in any way different from, or in addition to, the provisions of this chapter."

19. At the Subcommittee hearing, a Member of the Subcommittee identified the following consumer products as having denatonium benzoate in them to make them bitter: nail polish, hairspray, crayons, bubble bath, shampoo, eye

shadow, ink, hand sanitizer, windshield wash, laundry detergent, fabric softener, and perfume.

Have the manufacturers of any of these consumer products been provided immunity under Federal law from liability for any personal injury, death, property damage, or economic loss that results from the inclusion of denatonium benzoate in the consumer product? If so, please identify the consumer product and the specific statute that provides any such immunity from liability.

With the exception of windshield wash, Honeywell does not manufacture any of the identified household products and is not in the best position to describe the scope of liability of their manufacturers. Because of your positions on the House Energy and Commerce Committee, you and your staff may have a better understanding of the liability provisions passed under your Committee's jurisdiction in the past, with or without your support. We do suspect, however, that the manufacturers of the various products that contain denatonium benzoate include the ingredient under their own volition and have the ability to delete the substance or alter their products' composition without breaking federal law.

Prestone includes DB in windshield wash products in Oregon because the 1992 Oregon law requires us to do so. The state law, OR Rev. Statutes Title 36 431.870-915, contains liability protections as described in the statute:

"Limitation on liability; application. A manufacturer, distributor or seller of a toxic household product that is required to contain an aversive agent ... is not liable to any person for any personal injury, death or property damage that results from the inclusion of the aversive agent in the toxic household product."

- 20. Are you aware of any manufacturers of the following products that have been provided immunity from liability pursuant to Federal law for "damage to the environment (including natural resources)" that results from the inclusion of denatonium benzoate in the product:
  - a. Nail polish
  - b. Hairspray
  - c. Crayons
  - d. Bubble bath
  - e. Shampoo
  - f. Eye shadow
  - g. Ink
  - h. Hand sanitizer
  - i. Windshield wash
  - j. Laundry detergent
  - k. Fabric softener
  - 1. Perfume

# If so, please cite the specific statute and provision that provides the manufacturer of a product where DB has been added any such immunity from environmental liability.

As stated in response to the question above, with the exception of windshield wash, Honeywell does not manufacture any of the identified household products and is not in the best position to describe the scope of liability of their manufacturers. Because of your positions on the House Energy and Commerce Committee, you and your staff may have a better understanding of the liability provisions passed under your Committee's jurisdiction in the past, with or without your support. We do suspect, however, that the manufacturers of the various products that contain denatonium benzoate include the ingredient under their own volition and have the ability to delete the substance or alter their products' composition without breaking federal law.

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"Limitation on liability; application. A manufacturer, distributor or seller of a toxic household product that is required to contain an aversive agent ... is not liable to any person for any personal injury, death or property damage that results from the inclusion of the aversive agent in the toxic household product."

# RESPONSE FOR THE RECORD BY TOM BONACQUISTI, DIRECTOR OF WATER QUALITY AND PRODUCTION, FAIRFAX COUNTY WATER AUTHORITY, ON BEHALF OF AMERICAN WATER WORKS ASSOCIATION

June 10, 2006

The Honorable Paul E. Gilmor, Chairman Subcommittee on Environment and Hazardous Materials Committee on Energy and Commerce U.S. House of Representatives Washington, DC 20515

Dear Mr. Chairman:

Enclosed are the American Water Works Association (AWWA) responses to your questions asked in your letter of June 8, 2006, To Mr. Tom Bonaquisti, the AWWA witness at the hearing on H.R. 2567, The Antifreeze Bittering Act of 2005, on May 23, 2006.

We would be pleased provide you any additional information that you may need concerning drinking water issues. If you need additional information, please call me or Al Warburton, the Association Legislative Director, at 202-628-8303. Thank you for your time and kind consideration of the AWWA recommendations.

Sincerely,

Tom Center

Tom Curtis Deputy Executive Director for Government Affairs

### RESPONSES TO QUESTIONS ASKED BY THE HONORABLE PAUL E. GILMOR June 8, 2006 CONCERNING THE TESTIMONY OF THE AMERICAN WATER WORKS ASSOCIATION ON H.R. 2567, THE ANTIFREEZE BITTERING ACT OF 2005 PRESENTED BEFORE SUBCOMMITTEE ON ENVIRONMENT AND HAZARDOUS MATERIALS COMMITTEE ON ENERGY AND COMMERCE ON MAY 23, 2006

1. In your testimony, you state that information from the manufacturers of db show that their product is biodegradable and does not adhere to soil. However, EPA's testimony states that DB is "predicted to be resistant to biodegradation" and is "not predicted to readily migrate to soil" unless in very organically rich soils. This is a key fact because depending on whether DB is biodegradable relates directly to its absorption to sludge or other soils, making it more easily removable in a sanitary sewer system. Where is the source of your contradictory data and have your shared it with EPA?

AWWA RESPONSE: Our statement was contradicting the information contained in the manufacturers' Material Safety Data sheet (MSDS) which states that the DB is biodegradable and is not known to bioaccumulate. According to studies by Roy F. Westin, Inc., DB does NOT fully degrade in the environment. It was not removed during the sewage treatment process. It remained in the water and was not removed with the sludge (Study No. 92-042 - August 8, 1992; Study No. 92-051 - August 27, 1992; Study No. 92-052 - August 31, 1992). The SAE International Technical Paper No. 930587 states that in its study the denatorium ion was not removed by microbial degradation or by adsorption. This research confirms what both AWWA and EPA said on this point. However, Study No. 93-087 conducted by Roy F. Westin, Inc. concludes that DB does not "stick" to the soil. Rather, it stays in and travels with the groundwater. Therefore, it is reasonable to expect contamination problems as DB accumulates in the groundwater the net result is that the groundwater may become bitter and unpotable. These studies have been in the public domain for over tens years and we would expect that EPA researchers would have access to the studies. Our point was that there is conflicting and inconclusive data on the fate and transport of DB, particularly in water, which would make it very imprudent to provide far-reaching liability immunity to companies making or handling antifreeze containing DB.

2. Your statement reads: "It is also important to remember that antifreeze is used in large volumes in many industrial applications, such as deicing and large releases and widespread contamination of water supplies are possible." However, as I read subsection (d) and (e) of the newly created Section 25 in H.R. 2567, the bill caps its applicability to 55 gallons or less containers of antifreeze. I understand this to mean that we are only talking about containers that would be sold in the retail market. In addition, the user of the antifreeze is not covered under the liability shield in the bill. Do you share this reading of the bill?

**AWWA RESPONSE:** Our point in mentioning that antifreeze is used in large volumes in many industrial applications, was to illustrate that by mandating DB in all engine coolants or antifreeze, DB would be introduced into the environment in a larger scale in addition to the retail quantities of antifreeze and the current uses in certain

consumer products. By exempting one source of DB, the Congress is setting the stage for a constant battle between potential responsible parties (PRP) as to the source of the DB in the environment. Those parties that are not exempt would argue that the source of DB is from an exempted source. Our understanding of the bill is that the liability shield would extend down to include the distributor or seller, leaving the user to bear the liability for recovery of damages. In many, if not most of the cases, the end user is the financially least capable party in the chain to pay damages. The bill creates enough ambiguity for the PRPs that endless litigation concerning the source of DB may be the end result, making recovery of damages from any source problematic.

3. Under this legislation, the makers of antifreeze are responsible for any and all environmental damage caused by their product, including its main constituent, ethylene glycol, which EPA considers a toxic substance. Do you believe that DB-laced antifreeze could seep into groundwater or source water for a water system without any environmental effects from the antifreeze itself being in evidence? If this is not the case, since environmental liability exposure extends to both antifreeze and DB manufacturers, am I not correct that both parties would still be open to facing legal action?

**AWWA RESPONSE:** The Roy Westin, Inc. Study No. 93-087 assessed the results of pouring ethylene glycol on the ground and whether or not DB would stick to the soil or travel with the groundwater. In rural areas, some people dispose of used ethylene glycol by pouring it on the ground. The study concluded that there is minimal environmental impact when ethylene glycol is poured on the ground since it readily biodegrades into carbon dioxide and water in a matter of days and does not go into the groundwater in the form of the ethylene glycol compound. However, the study concludes that DB does not stick in the soil. Rather it stays in and travels with the groundwater. Therefore, it is reasonable to expect that when DB-laced antifreeze is poured on the ground, only the DB component of the antifreeze would be evident in the in the ground water or source water for a water system. Our understanding of the bill is that the manufacturer, processor, distributor, recycler, or seller of any antifreeze with the mandated level of DB would not be liable for damage to the environment resulting from DB in the antifreeze.

4. On April 18, 2003, the American Water Works Association issues a press release stating its support for the Drinking Water Standards Preservation Act. This bill would protect water utilities – much like antifreeze makers – from lawsuits, so long as they are in compliance with federal and state regulations. The drinking water bill seems to offer your members the same protections thing you are opposed to for another interest. How do you square this logic?

**AWWA RESPONSE:** As you noted, the American Water Works Association has endorsed the Drinking Water Standards Preservation Act (H.R. 1540). The bill would provide some liability protection fort public water systems that are incompliance with federal and state regulations. The difference between H.R. 1540 and other proposed liability immunity legislation is that public water systems are not introducing potential pollutants into the environment. Rather they are taking pollutants and microbes, many of them naturally occurring, out of the water. The thrust of the legislation is to protect the standard setting process rather than seeking liability immunity. AWWA believes very strongly that drinking water regulations should be based on the scientific process established in the Safe Drinking Water Act. States are free to make those standards more stringent through the state regulatory process. In all cases, the standards are scientifically based to be protective of public health within a reasonable risk range established by science. We are opposed to drinking water standards being set by judges and juries that have a limited capability to make regulatory determinations based on a scientific process.

5. Based on the testimony of other witnesses, it seems that the antifreeze industry has in the past not wanted a mandatory requirement for the addition of a bitterant in antifreeze. If the Congress requires the industry to put a substance in their product that they would otherwise not do, why shouldn't Congress excuse those companies from potential liability arising from that additional product? Wouldn't it be unfair to not allow this liability protection if the Congress supercedes a business decision?

**AWWA RESPONSE:** As stated in our testimony, AWWA has serious reservations about statutorily mandating a specific bittering agent and specific concentrations of that agent. We generally, believe that those kinds of decisions should be left to the regulatory process in which all available scientific data can be examined and decisions can be made with opportunity for public review and comment. Although our testimony focused on the limitation on liability, there would be no need for liability immunity if Congress did not require the industry to put a substance in their product that they would otherwise not do. We are not expert on how best to achieve the goal of preventing antifreeze poisoning or which bittering agent to use, but we do know that there are alternatives that should be examined. It would be far better for Congress to set a performance standard for the industry to achieve and let the industry or a regulatory process decide how to meet that performance standard. The industry then would not need liability protection because of a Congressional mandate.

6. According to other witnesses, DB has been and additive in certain consumer products for over 40 years. If that is the case, and if there was such a concern on what the chemical could do to water supplies, why hasn't AWWA taken the lead and funded studies regarding this additive? Wouldn't taking some action like this bolster your argument that your concerns here are significant and legitimate? Is AWWA aware of past groundwater, drinking water, or waste water contaminations caused directly by DB?

**AWWA RESPONSE:** The likelihood that DB would be a contaminant of widespread concern is largely a function of the volume released to the environment and the analytical method required to detect it at environmental concentrations.

Based on consultation with environmental laboratories it is unlikely that standard tests run by drinking water utilities would inadvertently identify the presence of DB. Currently there is not a consensus method for the determination of DB in environmental or finished water samples in ASTM, EPA, or Standard Methods. The only ASTM standard method for the denatonium ion is WK11066, Standard Test Method for Determination of Denatonium Ion in Engine Coolant by HPLC. Detection in water would require a gas chromatography / mass spectrometry or high performance liquid chromatography / mass spectrometry method. Given the low concentrations and the absence of a directed search specifically for DB using such a method its presence is unlikely to be detected.

AWWA has not undertaken any research into DB occurrence or removal as previously, there has not been a reason to be concerned about the release of this compound occurring in large quantities on a nation-wide basis. With limited exceptions, to-date, DB appears to be used in products that are formulated for use in very small quantities by consumers and in no instance that we could locate was the application taking place under an shield of immunity for any inadvertent harm caused by the release of the product. 7. In your testimony, you state that the denatonium ion which is responsible for the bitter taste is not easily biodegradable. Is it treatable in nay way? What would a wastewater or drinking water facility have to do to remove the ion from the water? How much would it cost? How much DB in the water supply would constitute a severe enough contamination to warrant the abandonment of that supply? If this law were passed, would that much DB even be added to the national supply of antifreeze?

**AWWA RESPONSE:** AWWA was not able to locate a treatability study on DB removal from drinking water. However, its chemical structure and properties provide a basis for some general observations regarding likely treatment approaches for DB. It does not appear that DB would be well removed in a conventional treatment plant (i.e., coagulation-sedimentation-filtration-disinfection). Conventional treatment is the collection of treatment unit processes that are typical of most surface water treatment plants in the U.S.

DB's solubility also suggests that it would not be well removed on activated carbon either making both powered activated carbon addition (PAC) and granular activated carbon (GAC) filtration unlikely treatment strategies. PAC is a common step taken to remove taste and odor compounds and GAC is a much more expensive process, but also one that has served as a benchmark best available technology (BAT) in the drinking water field for a number of years.

DB does appear amenable to oxidation using advanced oxidants such as ozone, ozone- hydrogen peroxide, and ultraviolet light-hydrogen peroxide. It is not clear without additional study if indeed advanced oxidants would work, what oxidant concentration and contact times would need to be employed or what disinfection byproducts will be created from such an oxidation approach. Ozone and other forms of advanced oxidation are only found in a limited fraction of water treatment plants at which concerns about microbial pollutants or other site-specific reasons led to their inclusion in the treatment train.

AWWA does not have the detailed information needed to estimate the cost of treating DB. But we do know from compliance with other major drinking water regulations, such as the Long-Term 2 Enhanced Surface Treatment Rule, that the cost for the capital cost associated with installing treatment and the annual operation and maintenance cost increase significantly for difficult to treat contaminants. The total national costs associated with DB would be a function of the specifics of actually treating for DB and the number of water treatment plants that found addition of other treatment necessary.

In this context it is also important to realize that many ground water supplies are of sufficiently high quality that they are not treated. The addition of one treatment to address DB would trigger additional regulatory requirements that in turn would elevate cost impacts. This aspect of adding additional treatment is a particular concern for small community (e.g., towns, villages, etc.) and non-community (e.g., churches, camp grounds, restaurants, gas stations, etc.) ground water systems.

This question also asks what level of DB poses a risk of abandoning a water supply. Solving this question is a local decision, which will need to take into account the availability of alternative water supplies, the viability of treatment options, and local resources. Historically and at present, taste and odor concerns are extremely important to drinking water utility customers as the public is very aware of water that tastes bad and they perceive it both as unpalatable and potentially harmful (e.g., the reasoning behind addition of a bittering agent like DB). Information provided on Bitrex indicates the aversive level in products like antifreeze is 30 ppm. Information provided by Market Actives, the U.S. distributor of Bitrex indicts that DB is Bitrex is aversively bitter at 1 to 10 parts per million (ppm) in water (http://www.marketactives.com/faq.html). It appears from the literature that the consumers would taste DB in water at much, much lower levels on the order of low part per billion levels if not lower. The question remains how much DB would be released in any one locale so as to contaminate the water supply at a discernable level. Water supplies are contaminated through both proper application of products (e.g., pesticides) and inadvertent releases ( e.g., storage tank failures, inappropriate disposal practices). There latter risks clearly exist. There are also likely instances where the former exist as well. For instance, ethylene glycol and other antifreeze compounds are applied to aircraft at airports as a part of deicing. This is an important process for aircraft safety. It also results in the release of antifreeze to storm water in significant quantities. Quantities sufficient to lead to taste and odor episodes come not only from the DB but also from the ethylene glycol.

# 8. What are the effects of antifreeze contamination of water supplies without the DB additive? Is it easily biodegradable? What kind of treatments would be necessary to remove regular antifreeze from water? How much do they cost? Has there ever been a case of a severe contamination of a water supply from antifreeze without the DB additive that caused the abandonment of that water supply?

**AWWA RESPONSE**: As stated in our response to Question 3, the Roy Westin, Inc. Study No. 93-087, concluded that there is minimal environmental impact when ethylene glycol without the DB additive is poured on the ground since the ethylene glycol readily biodegrades into carbon dioxide and water in a matter of days and does not go into the groundwater in the form of the ethylene glycol compound. We are unaware of any case of a severe contamination of a water supply from antifreeze without the DB additive that caused the abandonment of the water supply. However, there are instances where large-scale application of antifreeze at airports has resulted in taste and odor episodes at conventional surface water treatment facilities. This situation occurred at one of Fairfax Water's facilities prior to installation of ozone and movement of the water treatment plant's intake location.

### RESPONSE FOR THE RECORD BY JIM WILLIS, DIVISION DIRECTOR, CHEMICAL CONTROL DIVISION, OFFICE OF POLLUTION PREVENTION AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY

Responses to follow-up questions on U.S. EPA's May 23, 2006 testimony before the Subcommittee on the Environment and Hazardous Materials, at the legislative hearing on H.R. 2567, the Antifreeze Bittering Act of 2005.

#### The Honorable Paul E. Gillmor

# 1. Fourteen (14) years ago, when CPSC did a literature review of denatonium benzoate, CPSC found a general lack of information on bittering agents. With your testimony, does this mean that you consider the amount of information particularly as it relates to environmental fate-and-transport issues to have increased?

There is not an extensive database of toxicity or environmental fate information on DB, although there is a 2-year oral toxicity study in rats and several other oral studies in rats of shorter duration. Although the amount of publicly available data on the fate and transport of DB has not increased appreciably in 14 years, EPA's ability to predict the fate and transport of chemicals such as DB has improved considerably. EPA is confident that its predictions about the fate and transport of DB are reasonably accurate and would be supported by future measured test data.

2. The legislation being considered by our committee today contains a Federal requirement for antifreeze with 10 percent ethylene glycol to contain between 30 to 50 parts per million of DB. CPSC testified before the Senate Commerce Committee last July that "possible acute toxicity of DB does not appear to be a significant issue at the low levels used for aversion, such as the 30 to 50 parts per million range." Do you agree that human health is best protected from ingestion and the environment from releases at this level?

EPA cannot comment on whether DB at the 30 to 50 parts per million level would offer the best protection. That finding would seem to be a matter more within the purview of CPSC. However, according to our screening level analysis, EPA would agree that exposure to DB at such levels should not pose a significant risk to human health or the environment.

# 3. What are the environmental effects of plain antifreeze being released into water or soil? Would it be possible to have bittered antifreeze released into the environment and only have the environmental damage caused by the bittering agent?

The environmental effects of plain antifreeze being released into water and soil are low. Plain antifreeze is easily biodegradable, i.e., is not persistent. The environmental damage caused by the bittering agent if added to antifreeze and released with antifreeze is expected to be low. Based on structure-activity relationship (SAR) analysis, DB is expected to have low toxicity to fish and aquatic invertebrates and moderate toxicity to green algae. In a natural environment, potential exposure to green algae would be reduced due to rapid adsorption of the cation of DB to organic matter found in water and soils. Once the cation is adsorbed to organic matter it is less bioavailable, thereby significantly mitigating the potential for exposure to toxic levels of DB.

# 4. Has EPA conducted a full risk assessment on DB? Why? How reliable is the screening-level toxicity and environmental exposure estimation techniques that EPA has used on DB?

At this time, the Agency does not consider the low expected production volume and associated low environmental releases and exposure to support the need for a detailed risk assessment. The Agency is reasonably confident of the results of the modeling which EPA performed in its screening level fate and toxicity assessment but would nonetheless benefit from obtaining copies of existing studies on DB held by industry.

# 5. Do you think it is a problem if DB gets into groundwater or not? If DB is not filtered out by a drinking water system, since it does not biodegrade, is it a threat to health or the environment?

Because of DB's low production volume and pattern of use and storage, there would be relatively few opportunities for an environmental release that could reach groundwater in significant quantities. EPA does not expect DB released to soil to reach groundwater because of its tendency to adsorb to soil and its extremely slow soil mobility rate. Furthermore, in the event that DB did eventually reach a water supply, we would expect it to be filtered out by treatment. Considering the low production volume and pattern of use and storage and the results of our screening analysis, we believe that DB is unlikely to pose a significant risk even if not filtered out.

6. Some people have raised questions about whether it is possible to get DB information since the major manufacturers of this chemical are based overseas and past attempts by private parties have been met with resistance due to confidential business information claims. Do you have the same problems with getting this data and do you believed that DB manufacturers would be subject to "personal jurisdiction" in the event of claims of damages caused by DB?

If needed, EPA could use its reporting authority under TSCA §8d to obtain existing studies from manufacturers and processors.

#### The Honorable John D. Dingell and the Honorable Hilda L. Solis

### 1. Is it correct that there is only one registered pesticide where denatonium benzoate (DB) is an active ingredient?

Currently, there are **two** products registered with the active ingredient, DB (bitrex). Each product contains 0.2% active ingredient.

## Is that registered use a deer repellent sold under the brand name *Tree Guard* for use on shrubs and certain types of trees?

The two registered products are:

1. Tree Guard®, EPA Reg. No. 66676-1 (registered January 30, 1996, to reduce feeding by deer on trees, shrubs, flowers, and other ornamental plants), and

2. Fooey®, EPA Reg. No. 680086-7 (registered August 10, 2005, to reduce chewing, biting and licking by dogs, cats, horses, and other animals)

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### 2. Is it correct that the use restrictions for *Tree Guard* include the following?

- Do not use on food or feed crops
- Do not apply aerially
- Do not apply product through any type of irrigation system or hose proportioner applicator
- Do not apply directly to water, to areas where surface water is present, or to inter-tidal areas below the mean high water mark
- Do not clean equipment or dispose of equipment wash waters in a manner that will contaminate water resources or arable land.

Yes, the use restrictions for *Tree Guard* include the five restrictions listed in your question.

The use restrictions for *Fooey* include these two restrictions:

- Do not apply directly to water.
- Do not clean equipment or dispose of equipment wash waters in a manner that will contaminate water resources or arable land.

The use restrictions for *Fooey* are fewer than those for *Tree Guard* because the use pattern is more limited.

# 3. Is it correct that the Environmental Protection Agency (EPA) is scheduled to review the registration for *Tree Guard* in June 2006? If so, what information and data will EPA request on the bitterant denatonium benzoate and what type of scientific review will be conducted?

Over the next two years, the Agency will review the database for the active ingredient, denatonium benzoate, and determine whether there are sufficient data on the active ingredient. If not, the Agency will proceed to call in any missing data on the individual products themselves. After the necessary data have been submitted and reviewed, the Agency will be able to determine whether this pesticide meets the requirements for reregistration. EPA expects to complete this process by September 2008.

To support the current uses of the active ingredient, EPA would normally require basic chemistry, toxicity, worker exposure, and environmental fate and effects data. The final list of requirements will be determined during the next two years. EPA will review the available data for denatonium benzoate and conduct ecological and human health risk assessments based on those studies.

# 4. Based on your current knowledge, do you expect the registrant for *Tree Guard* to seek to re-register this pesticide and submit the necessary data for an appropriate scientific review?

At this time, we are unaware of the plans of the two registrants to seek reregistration of this pesticide and submit the necessary data for an appropriate scientific review.

5. Is it correct that EPA staff conducted its computer-based modeling estimation technique on denatonium benzoate (bitrex) in the fall of 2005 at the request of an official of the Consumer Specialty Products Association?

6. Did officials of Honeywell or the Consumer Specialty Products Association ever provide EPA with the independent scientific studies which they possessed that determined that DB does not biodegrade and is not removed during the processes used to treat waste water at publicly-owned treatment facilities? If so, please specify the date when such studies were provided to EPA.

EPA did not receive the full biodegradation and soil adsorption study reports, along with other review articles and assessments, until the May 23, 2006 Subcommittee hearing. We are currently reviewing these studies.

# 7. At the Subcommittee hearing, you testified that "we have reviewed available data made known to us." Please specify what actual scientific studies were available to EPA and identify who provided them.

The Agency performed a general literature review for DB. There is not an extensive database of published toxicity values or environmental fate information, so the Agency relied on predictive assessments and the results of the 2-year oral study in rats and other studies summarized in the Food and Drug Administration's (FDA) FR notice of October 17, 1980 (45 FR 69125), "Establishment of Monographs for Nailbiting and Thumbsucking Deterrent and Ingrown Toenail Relief Drug Products for Over-the-Counter Human Use."

### 8. Has EPA attempted to obtain environmental fate and transport data from the manufacturers of denatonium benzoate? If so, please describe the circumstances.

No. The Agency has not attempted to obtain data from the manufacturers of DB. Following the hearing, the Consumer Specialty Products Association did provide us the studies referred to in Question and Answer 6 above.

### 9. Is EPA currently conducting any actual scientific studies on the environmental fate and transport characteristics of denatonium benzoate?

Given the low expected production volume and associated low environmental releases and exposure, the results of its screening level assessment, and pending review of the studies provided by industry, EPA has not identified a priority need for it to conduct additional studies.

10. Statements were made at the hearing that denatonium benzoate was used in the following consumer products: nail polish, hairspray, crayons, bubble bath, shampoo, eye shadow, ink, hand sanitizer windshield wash, laundry detergent, fabric softener, and perfume. Do the manufacturers of any of the above mentioned products have an exemption or immunity from Superfund liability (including natural resources damages) that results from the inclusion of denatonium benzoate in the consumer product? If so, please cite the specific statutory provision that provides the exemption or immunity from environmental liability (including natural resource damages).

No. The exemption from liability that would be provided by sec. 25(c) applies only to "a manufacturer, processor, distributor, recycler, or seller of an engine coolant or antifreeze that is required to contain an aversive agent under subsection (a)..."

11. What other laws administered by EPA could be affected by the liability waiver for "damage to the environment" contained in Section 2 of H.R. 2567?

EPA does not administer the Federal Hazardous Substances Act (FHSA) and thus does not have primary interpretive authority regarding the statute or amendments thereto. Based on what appears to be the most straightforward reading, however, EPA would not expect the liability waiver for damage to the environment contained in Section 2 of H.R. 2567 to significantly impact laws administered by EPA. Since the definition of "person" in FHSA Section 2 does not appear to include government agencies, the waiver of liability "to any person" would not appear to provide protection from possible EPA enforcement actions for regulatory violations. In addition, although several statutes administered by EPA provide for "citizen suits" to enforce the statutes, in those cases the citizens stand in the shoes of the Government, and the remedy available under these provisions is generally an injunction against further violations or penalties paid to the U.S. Treasury, not an award to the plaintiff for environmental damage. The Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), however, does make certain persons liable for the cost of cleaning up releases of hazardous substances, and that liability can in some cases be to private parties. If the term "damage to the environment" were interpreted to include such cleanup costs, and a bittering agent were a CERCLA hazardous substance, CERCLA liability could potentially be affected.

12. Could a spill of denatonium benzoate by a manufacturer, processor, distributor, or recycler of an engine coolant or antifreeze that affects navigable waterways or results in an imminent and substantial endangerment to human health or the environment potentially involve the statutory authorities of the (1) Clean Water Act, (2) Solid Waste Disposal Act or (3) Safe Drinking Water Act? If not, please explain why not.

A spill of denatonium benzoate that results in an imminent and substantial endangerment could involve statutory authority under the Resource Conservation and Recovery Act (RCRA). EPA could require a person responsible for a spill that results in an imminent and substantial endangerment to remediate the spill under the authority of RCRA sec. 7003.

13. Is it correct that Section 2 of H.R. 2567 would provide immunity from liability for manufacturer, processor, distributor, or recycler of an engine coolant or antifreeze under the Clean Water Act, the Safe Drinking Water Act, and the Solid Waste Disposal Act for damages to the environment caused by spills of denatonium benzoate that results from the inclusion of denatonium benzoate in any engine coolant or antifreeze?

H.R. 2567 states that such persons "shall not be liable to any person for any personal injury, death, property damage, damage to the environment (including natural resources), or economic loss that results from the inclusion of denatonium benzoate in any engine coolant or antifreeze, provided that the inclusion of denatonium benzoate is present in concentrations mandated by subsection (a)." These persons as described in the bill would be exempt from liability under the Clean Water Act, Safe Drinking Water Act, and Solid Waste Disposal Act, but only if the denatonium benzoate were present in concentrations mandated by subsection (a).

14. At the time officials of the Consumer Specialty Products Association asked EPA to provide a screening level analysis of denatonium benzoate, did any EPA officials ask the industry representatives whether they were aware of or possessed actual

## scientific studies that had been performed on the toxicity or environmental fate and transport of denatonium benzoate? If not, please explain why not.

The meeting in question was in September, 2005. EPA did not request further data because the focus and the purpose of the meeting was to discuss the structure-activity relationship (SAR) analysis approach to assessing DB.

# 15. With respect to the use of DB in certain consumer products, do the environmental exposure risks depend and differ on whether it binds to and the manner it is used in the underlying product (such as nail polish or crayons), and in the manner in which the underlying product is itself disposed of?

Yes, potential health and environmental risks are related directly to potential for release and exposure to the chemical. Generally, the risk posed by a chemical is related to its hazard (toxicity) and exposure levels. This is the reason that soil adsorption (which limits DB's mobility in soil) and patterns of use are important for DB. It is not expected to migrate through soil to groundwater and (for the consumer use in one gallon containers) is not stored in large underground tanks, where the potential for spillage and contamination are increased.

### 16. Does EPA interpret H.R. 2567 as applying to airplane de-icing operations?

EPA understands this legislation as applying only to consumer uses, in small containers, as opposed to airplane de-icing, with associated large volume use and storage and potential for accidental spills.

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