Barbara Christianson <BChristianson@lawbc.com>
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To: Lorraine D. Hunt OIRA BC RPT/OMB/EOP@EOP

cc:
Subject: RRTF -- Comments on Draft 2003 Report to Congress on the Costs an d Benefits of Federal Regulations

Appended are comments from the Rodenticide Registrants Task Force regarding the *Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations*. Please let us know if you have any questions.

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Barbara Christianson

Legal Secretary

BERGESON & CAMPBELL, P.C.

1203 Nineteenth Street, NW

Suite 300

Washington, D.C. 20036-2401

bchristianson@lawbc.com

(202) 557-3807 (phone)

(202) 557-3836 (fax)

Please visit our Web Site at http://www.lawbc.com

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RRTF Rodenticide Registrants Task Force

Bergeson & Campbell, P.C.
1203 Nineteenth Street, N.W.
Suite 300
Washington, D.C. 20036-2401
Tel: (202) 557-3800
Fax: (202) 557-3836

May 5, 2003

Via E-Mail

Ms. Lorraine Hunt
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB
Room 10202
725 17th Street, N.W.
Washington, D.C. 20503

Re: *Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations*

Dear Ms. Hunt:

The Rodenticide Registrants Task Force (RRTF)[1] submits these comments to the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) in response to the *Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations* (Report).[2] The RRTF welcomes OMB's requests for comments on this Report, and particularly appreciates OMB's interest in receiving comments on the federal government's approaches to analysis and management of emerging risks and how the government balances precautionary approaches to health, safety and environmental risks with other interests such as economic growth and technological innovation.

The RRTF's comments focus on OMB's request for comment on "[e]xamples of approaches in human and ecological risk assessment and management methods addressed by U.S. regulatory agencies (*e.g.,* consumer product safety, drug approval, pesticide registration, protection

[1] The RRTF is composed of eight rodenticide registrants. Members are: ADM Alliance Nutrition, Inc.; Bacon Products, Inc.; Bell Laboratories, Inc.; California Department of Food and Agriculture; Hacco, Inc.; LiphaTech, Inc.; Reckitt Benckiser, Inc.; and Syngenta Crop Protection, Inc.

[2] 68 Fed. Reg. 5492 (Feb. 3, 2003).

of endangered species) which appear unbalanced."[3] To address this issue, these comments describe as an example of an unbalanced document the U.S. Environmental Protection Agency's (EPA) preliminary comparative "ecological risk" assessment of rodenticides (PCA), which was recently issued for public comment.

EPA states that the PCA compares the "risks" of various rodenticide products when it clearly does not do so. The PCA is a scientifically, legally, and technically flawed document that is being treated procedurally as an ecological risk assessment, despite the fact that it is merely a relative ranking of hazard of products with varied modes of action that fails to evaluate the likelihood of exposure for the many different use patterns. Even absent the flaws in the PCA, it is inappropriate and reflects an unbalanced approach to ecological risk assessment and management for EPA to use a document that fails to assess the ecological risks of any rodenticide as a stepping stone to the imposition of inappropriate, ill-conceived, and unsupported mitigation measures that could reduce or eliminate pest control options. It is critical that EPA actions based on the identification of an ecological "risk" not deprive users of solutions for the economical and effective control of disease-bearing pests without a sound scientific basis.

The RRTF hopes this example, which is described in more detail below, will assist OMB and others in the Executive Office who are seeking to improve federal regulatory analysis and management. The RRTF looks forward to working with OMB on this and similar matters in the future.

EPA Has Characterized the PCA As a Comparative "Ecological Risk Assessment" and Has Stated That the PCA Will Be Treated Procedurally As an Ecological Risk Assessment

EPA issued on January 29, 2003, a *Federal Register* notice announcing "the availability of the preliminary comparative ecological assessment for nine rodenticides," and establishing a comment period.[4] The notice simply announces the availability of the PCA -- available on EPA's website[5] -- and does not state its context. The document is entitled "Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach." While the title of the document does not refer to "ecological risk," EPA's Special Review and Reregistration Division (SRRD) has made clear -- through the *Federal Register* notice, the docket, EPA's website, and oral statements by SRRD representatives -- its position that this document is an "ecological risk assessment" and will be treated procedurally as such.

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3 68 Fed. Reg. at 5499.

4 68 Fed. Reg. 4468 (Jan. 29, 2003).

5 *See* http://www.epa.gov/pesticides/rodenticidecluster/.

According to SRRD representatives, this "preliminary comparative ecological risk assessment" is in the multi-phase process established by EPA and reserved for consideration of "risk assessments." As acknowledged by SRRD representatives, the next phases of that process are solicitation of "risk management ideas" and development of "risk management strategies." As the RRTF will further outline in its forthcoming comments on the PCA,[6] because EPA's PCA is not an ecological risk assessment (despite EPA's attempts to label it as one), it is inconsistent with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA guidance, and sound science -- and reflects an unbalanced approach to ecological risk assessment and risk management -- for EPA to characterize the PCA as an ecological risk assessment.

The PCA Is Not an Ecological Risk Assessment and Cannot Appropriately Be Relied Upon As a Scientifically Defensible Ecological Risk Assessment

The PCA is not an ecological risk assessment, and is technically and legally flawed. The RRTF's technical concerns with the PCA include the following:

- EPA's "comparative approach" provides only a relative ranking of hazard, and fails to compare even "potential" risk.
- The PCA's approach to estimating exposure is fundamentally flawed and, at most, provides a redundant ranking of hazard.
- EPA's PCA was not prepared in a manner consistent with the methodology used for other EPA ecological risk assessments or comparative ecological risk assessments, nor does it have stated purposes consistent with those of the other comparative assessments or with guidance for such reports issued by the Scientific Advisory Panel (SAP).
- EPA has inappropriately "adapted" those other comparative methodologies and has incorrectly defined and used "measures of effect" for rodenticides, resulting in a scientifically indefensible ranking of rodenticides.
- EPA's sensitivity analysis fails to reflect accurately the uncertainty inherent in the comparative analysis model methodology, resulting in a weak basis for even a qualitative weight of evidence argument for ranking these nine rodenticides.

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6 Those comments have not yet been filed. EPA extended the original comment deadline to May 30, 2003. We will supplement these comments with a copy of the RRTF's final, filed comments.

- EPA uses laboratory secondary toxicity studies to characterize potential secondary risk, which misstates hazard as risk.

- EPA's characterization of any rodenticide residues as rodenticide "incidents" is inappropriate and scientifically indefensible.

EPA must correct the substantial scientific flaws in the PCA to meet its legal obligations under FIFRA, the Information Quality Act, and the Administrative Procedure Act. As currently drafted, the PCA -- which is replete with scientific deficiencies -- fails to comply with the following legal obligations:

- EPA's PCA is not an ecological risk assessment and should neither be characterized as one nor used for the same purposes as a scientifically defensible risk assessment. It is inappropriate and unlawful for EPA to insert the PCA in a multi-phase process reserved for consideration of "risk assessments" and, ultimately, solicitation of "risk management ideas" and development of "risk management strategies."

- EPA has failed to follow law, its own policies, and required procedures. EPA has failed to consider all relevant information as required by law; it has failed to follow Section 515 of the FY 2001 Treasury and General Government Appropriations Act (the Information Quality Act); it has failed to follow established EPA peer review procedures; and it has failed to follow FIFRA requirements that it consider the benefits of rodenticides.

These technical and legal concerns will be outlined in detail in the RRTF's forthcoming comments on the PCA, a copy of which will be provided to you.

The PCA Cannot Be Used As a Stepping Stone to the Imposition of Mitigation Measures

The RRTF is very concerned that, despite these many scientific and legal flaws, the PCA will inappropriately be used as a stepping stone to the imposition of inappropriate, ill-conceived, and unsupported mitigation measures that could reduce or eliminate pest control options. It is critical that EPA actions not deprive users of solutions for the economical and effective control of disease-bearing pests without a sound scientific basis.

Rodenticides play a critical role in pest control and thus in ensuring public health. Rats and mice, two of the many destructive disease carrying rodents that RRTF member companies' products control, spread over 35 diseases worldwide, some of which can be fatal, *e.g.,* Hantavirus, Rat Bite Fever, and Leptospirosis. The diseases are spread in many ways: directly through bite wounds; through contamination of human food, water, or habitation by rodent urine or feces; or by

way of ticks, mites, fleas, and other biting insects that transmit the infection to humans after feeding on infected rodents. As noted by EPA's Rodenticide Stakeholder Workgroup (RSW), a stakeholder group that convened in 1999 to advise EPA on certain rodenticide issues:[7]

> The societal value of rodent control is high regardless of one's position on the use of rodenticides. . . . The benefits of keeping rodent infestations in check through the proper use of rodenticides or other alternative measures are many fold. Although rodenticides are just one of many ways to control rodents in the home, they occupy an important niche in today's increasingly urban population. As a group, the anticoagulant rodenticides are a widely-used, efficacious means to control rats and mice in the home when used as directed on the label.[8]

The District of Columbia has itself been the subject of considerable national attention due to the rodent problems it has experienced over the past several years.[9] The District is not alone, as a growing number of major urban areas, including New York and Chicago, have been similarly plagued by out-of-control rodent infestations.[10] Clearly, rodent control is an issue of significant public health concern.

EPA's SRRD asserts that the PCA is part of the multi-phase process that culminates in "risk management strategies." EPA thus believes that this document can serve as the basis for the identification of mitigation measures. EPA has broad authority to mitigate "risks" it believes unreasonable, including product cancellation, use restrictions, product use cancellations, and related measures, all of which necessarily result in diminished product use and likely higher product cost.

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7 The RSW was composed of representatives from the general public, the medical community, public interest groups, industry, and government agencies and bureaus. Its purpose was "to provide advice and recommendations to the EPA on a pesticide exposure issue involving children." RSW, *Recommendations for Managing Rodenticide Exposures To Children in the Home*, Subcommittee Report to the Pesticide Program Dialogue Committee (PPDC) for consideration by the U.S. Environmental Protection Agency (Nov. 15, 2000) at 2.

8 *Id*. at 26.

9 "Weather worsens rat 'war' in D.C.: Will city be able to win the battle?," *Washington Times*, at A01 (Apr. 04, 2002).

10 *See, e.g.,* "Obadele: CHA rebuilding plan fails because human aspect ignored," *Chicago Defender,* at 3 (Aug. 28, 2001); "The Rat Patrol," *New York Times*, at Sec. 14 p.1 (July 25, 1999).

Despite EPA's assertions to the contrary, the risk assessment methodology used by EPA in preparing the PCA is generally neither legally nor scientifically valid for assessing "risks" and any mitigation measures based on the PCA would be insupportable.

Further, as the RRTF will outline in detail in its forthcoming comments, the PCA is not consistent with the Information Quality Act, OMB's information quality guidelines implementing the legislation, or EPA's own information quality guidelines.[11] The RRTF urges OMB to consult with EPA and inquire about the PCA, and to review the extensive comments the RRTF has submitted on it to date. The PCA cannot under any circumstances serve as the predicate for the identification of risk mitigation measures, as it fails to assess the risks presented by any rodenticide. If it were to serve as such a predicate, valuable products essentially for the control of public health threats will be compromised at the risk of inviting perhaps significant public harm. It is critical that EPA actions not deprive users of solutions for the economical and effective control of disease-bearing pests without a sound scientific basis.

We hope this information is helpful. Please call if you have any questions.

Sincerely,

Lynn L. Bergeson
Eileen Salathé Gernhard

Lynn L. Bergeson, Esquire
Eileen Salathé Gernhard, Esquire
For the Rodenticide Registrants Task Force

cc: Rodenticide Registrants Task Force (via e-mail)

[11] *See* 67 Fed. Reg. 369 (Jan. 3, 2002) (republished to correct errors at 67 Fed. Reg. 8451 (Feb. 22, 2002)); http://www.epa.gov/oei/qualityguidelines/EPA-OEI-IQG-FINAL-10.2.pdf.